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Preface

Introduction

Instrument description

Quintus 5-part hematology analyzer produced by Boule Medical for human application.

Serial number

Serial number is located on the rear of the instrument and in the Information screen.

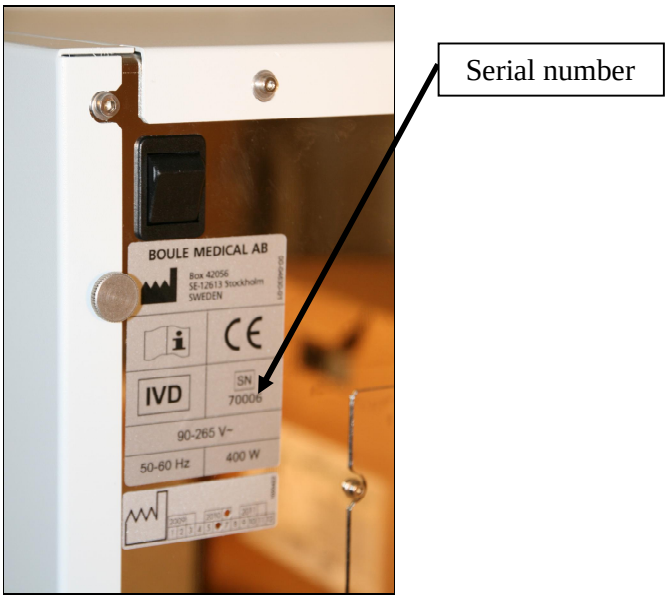


Figure 1.1

Software version

The software version is found in the Diagnostic > Information screen.

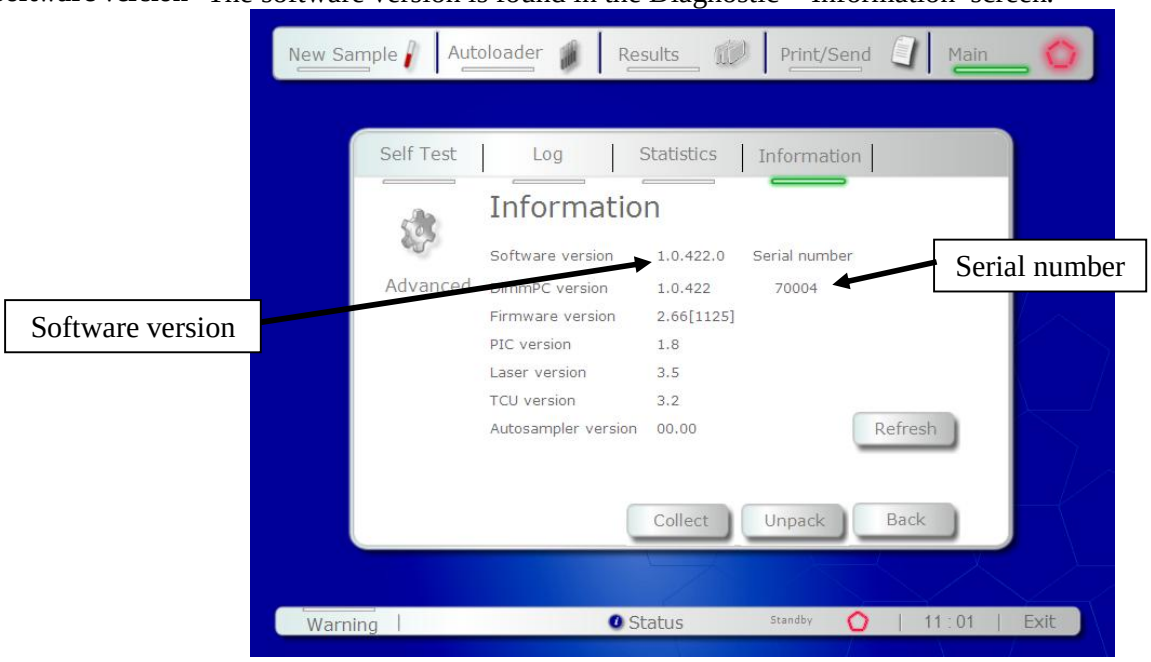


Figure 1.2

Additional Documentation

Additional documentation is available from your authorized distributor. Current additional documentation is listed below:

- Service Manual
- Basic Hematology
- Product data sheets

Operator requirements

The following operator requirements must be fulfilled before operating the Quintus hematology system.

- Basic skills in a laboratory environment.
- Basic skills in hematology.
- Awareness of IVD (EU)/FDA (US) requirements regarding laboratory equipment.
- The operator must read and understand this manual.

Optional accessories and consumables

Accessories and consumable lists are available from your local distributor.

Manufacturer's details

Boule Medical AB
P.O. Box 42056
SE-126 13 Stockholm
Sweden

Telephone number: +46 8 744 77 00
Fax number: +46 8 744 77 20
Email: info@bm.boule.se

Distributor details

Distributors are listed on http://www.boule.se

International standards and regulations

EN591:2001
IVD 98/79/EG
SSEN 61010-2-101 (Low Voltage Directive 2006/95/EC)
EN 61326 (2006) (EMC 2004/108/EC)
Standards harmonized with FDA

Date of Issue

October 2010 Article no: 1504308

Software Versions

Descriptions contained herein are relevant to Quintus, software versions:

- Main (upper-part) software: 1.0.432;
- OPN (DimmPC) software: 1.0.432;
- Firmware: 2.63 (1122)
- PIC software: 1.7
- Laser software: 3.5

Section 1: Safety Instructions

Section Overview

Introduction

This section describes the safety features and warnings associated with the Quintus system.

Contents

This section contains the following topics:

Topic	See Page
Intended Use	5
Safety Instructions	6
Biohazards	6
Emergency Procedures	7
Warning Signs in Manual	7
Instrument Signage	8

1.1 Intended Use

Description

The Quintus is a fully automatic hematology analyzer intended for in vitro diagnostic testing of blood specimens under laboratory conditions.

Operator Requirements

Operator must have basic laboratory skills and be aware of good laboratory practice.

Warranty limitations

- Service must be performed by Boule Medical AB (hereafter referred to as Boule), or by service personnel authorized by Boule.
- Use only original spare parts and Boule authorized reagents, blood controls, calibrators and cleaners. (If these products are substituted it may void your warranty)
- Operators and laboratory supervisors are responsible that Boule products are operated and maintained according to the procedures described in manuals, control inserts and technical bulletins.

Warranty limitations in depth

- Each Boule system is tested using recommended reagents, blood controls, calibrators and cleaners. All performance claims are generated as part of this complete system.
- Boule products do NOT make diagnoses on patients. Boule intends its diagnostic products (systems, software and hardware) to be used to collect data reflecting the patient's hematological status. This data, in conjunction with other diagnostic information and the evaluation of the patient's condition, can be used by a trained clinician to establish a patient's diagnosis and to define clinical treatment.

1.2 Safety Instruction

Description

Boule incorporates safety features within the instrument in order to protect the operator from injury, the instrument from damage and the test results from inaccuracies.

Restrictions

In order to insure the safety of the operator and instrument follow the instruction below:

- Do not use the instrument outdoors.
- Do no modify the instrument.
- Do not remove the outer covers. (Authorized personnel only)
- Do not use the instrument for other purposes than described in this manual.
- Do not spill blood or other fluids on the instrument in such a way that it can leak through the instrument casing. (This might result in electrical malfunction or personal injury)

Important

- Unauthorized modification of the instrument might result in erroneous results or risk for electrical shock.
- Spilling fluids into the instrument might cause electrical malfunction and/or personal injury.

Handling of reagents

- If a reagent comes in contact with eyes, rinse with running water for several minutes. If symptoms occur seek medical attention.
- If the reagent comes into contact with skin, wash affected area with water.
- If swallowed, rinse out mouth. If persistent symptoms occur seek medical attention.
- Refer to MSDS at www.boule.se for further details.

1.3 Biohazards

Description

As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, blood controls, calibrators and waste these products should be handled as potentially biohazardous.

Support documentation

- Protection of Laboratory Workers From Infectious Disease Transmitted by occupationally acquired infections – 2nd Edition, Approved Guidelines (2001) Document M29-T2 promulgated by the Clinical and Laboratory Standards Institute, CLSI (NCCLS).
- Follow local regulatory documentation.

Handling of biohazardous material

- Always wear protective gloves and goggles. Follow local regulations.
- Handle samples with great care. Report incident according to local regulations.
- Do not touch the waste liquid when discarding waste.

Mandatory Action

- If blood comes in contact with eyes or open cut, wash affected area with plenty of water.
- If the waste liquid is inadvertently touched, wash affected area with disinfectant solution first and follow with soap.

1.4 Emergency Procedure

In case of emergency

If there are any obvious signs of malfunction such as smoke or liquid leaking out of the instrument proceed as follows:

Step	Action
1	Disconnect the main power supply immediately by pulling out the cord from the main supply.
2	Contact your authorized distributor.

1.5 Warning Signs in Manual

Warning Signs

The following warning signs in the manual are used to identify possible hazards and to call on the operator's attention to this condition.

Sign	Function
Warning	Indicates operation procedures that could result in personal injury or loss of life if not correctly followed.
Caution	Indicates operation procedures that could result in damage or destruction of equipment if not strictly observed.
Important	Emphasizes operating procedures that must be followed to avoid erroneous results.
Mandatory Action	Indicates that protective clothing, gloves or goggles must be used when performing described procedures.

1.6 Instrument Signage

Description Signs placed on the instrument define areas that need special attention or areas that contain danger. See IVD Symbol Table on page 9.

Signs on equipment

Figure 1.3

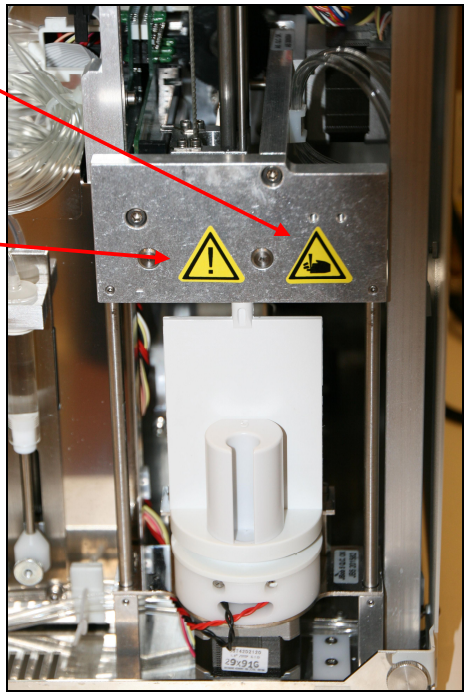


Figure 1.4

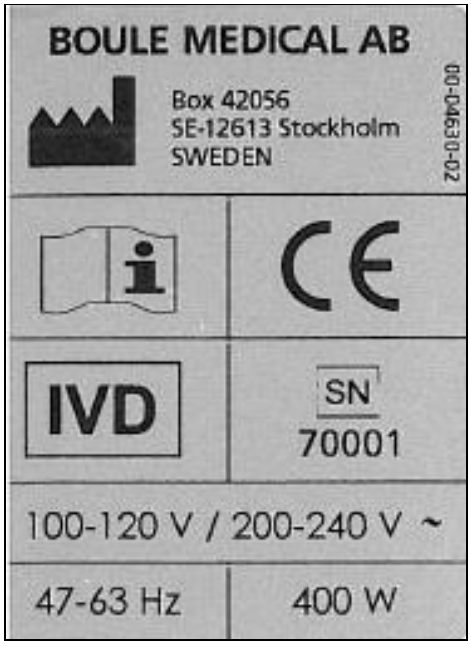


Figure 1.5

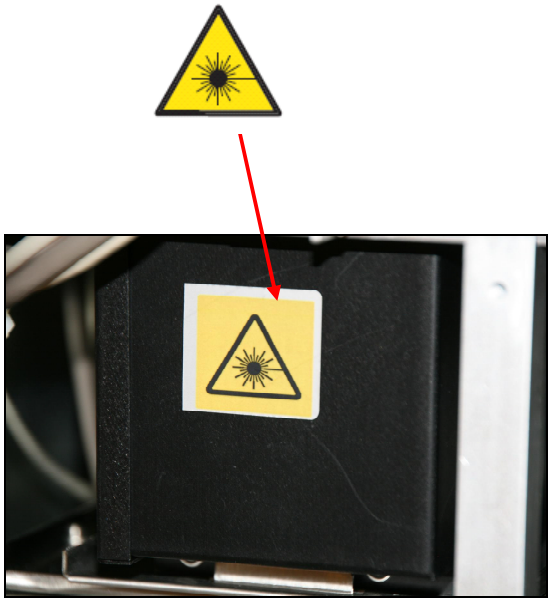


Figure 1.6

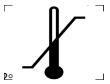
GB DE ES IT FR DK GR SE PO PL NO EST CZ CN	Caution,consult instruction for use Achtung, Gebrauchsanweisung beachten Atención,ver instrucciones de uso Attenzione, vedere le istruzioni per l'uso Attention voir notice d'instructions Forsigtig se brugsanvisning Προειδοποίηση, συμβουλευτείτε τα συνοδά έντυπα Varsamhet, se bruksanvisning Atenção, ler as instruções de utilização Ostrzeżenie – skonsultować z instrukcją obsługi Forsiktig! Sjekk instruks nøye før bruk Hoiatus, vt. infot kasutusjuhendist Upozornění, přečtěte si návod k použití 注意，须参阅使用说明	Biological risk Biologissche Risiken Riesgo biológico Rischio biologico Risques biologiques Biologisk fare Βιολογικοί κίνδυνοι Biologisk risk Risco biológico Ryzyko wystąpienia skażenia biologcznego Biologisk risiko Bioloogiline risk Biologické riziko 生物危害	Consult Instructions for Use- Gebrauchsanweisung beachten Consulte las instrucciones de uso Consultare le istruzioni per l'uso Consulter les instructions d'utilisation Se brugsanvisning Συμβουλευτείτε τις οδηγίες χρήσης Se bruksanvisning Consultar as instruções de utilização Skonsultować z instrukcją obsługi Sjekk instruks før bruk Tutvu kasutusjuhendiga Přečtěte si návod k použití 请参阅使用说明	Use by Verwendbar bis Fecha de caducidad Utilizzare entro Utiliser jusque Holdbar til Ημερομηνία λήξης Använd före Data de validade Uzyc przed Holdbarhet Kasutada enne Datum expirace 有效期
	EC REP			LOT
GB DE ES IT FR DK GR SE PO PL NO EST CZ CN	Authorized representative in the EC Bevollmächtigter in der Europäischen Gemeinschaft Representante autorizado en la Comunidad Europea Mandatario nella Comunità Europea Mandataire dans la Communauté européenne Repræsentant i det Europæiske Fællesskab Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα Auktoriserad representant inom Europeiska Gemenskapen Representante autorizado na Comunidade Europeia Autoryzowany Przedstawiciel w Unii Europejskiej Autorisert representant i EC Autoriseeritud esindaja EU-s Autorizovaný zástupce výrobce pro EU EC授权代表	Temperature limitation Zulässiger Temperaturbereich Limite de temperatura Limiti di temperatura Limites de température Temperaturbegrænsning Περιορισμοί θερμοκρασίας Temperaturbegränsning Limites de temperatura Zakres temeratury przechowywania Temperaturbegrensning Temperatuuri piirang Limitující teploty 温度限制	Manufacturer Hersteller Fabricante Fabbricante Fabricant Producent Κατασκευαστής Tillverkare Fabricante Producent Produsent Tootja Výrobce 制造商	Lot number Chargenbezeichnung Código de lote Codice del lotto Code du lot Lotnummer Αριθμός Παρτίδας Lotnummer Número de lote Numer serii Lot nummer Lot number Číslo šarže 批号
	IVD	CONTROL H 20	CONT	CONTROL
GB DE ES IT FR DK GR SE PO PL NO EST CZ CN	In Vitro Diagnostic Medical Device In Vitro Diagnostikum Producto sanitario para diagnóstico in vitro Dispositivo medico-diagnostico in vitro Dispositif médical de diagnostic in vitro Medicinsk udstyr til in vitro-diagnostik In Vitro Διαγνωστικό Ιατροτεχνολογικό προϊόν In vitro diagnostik Dispositivo médico para diagnóstico in vitro Produkt medyczny do diagnostistyki in vitro In vitro bruk In Vitro Diagnostika Meditsiini seade Diagnostické činidlo In Vitro 体外诊断产品	High control, 20 parameters Hoch Kontrolle, 20 Parameter Control alto, 20 parámetros Controllo alto. 20 parametri Contrôle haut, 20 paramètres Høj Kontrol, 20 parametrer Πρότυπο ελέγχου Υψηλό, 20 Παράμετρος Hög kontroll, 20 parametrar Controlo alto, 20 parâmetros Poziomie wysokim kontrolny, 20-parametrowy Kontroll; 20 parametere, høy Kõrge kontroll, 20 parameetrit Vysoká kontrola, 20 parametrů 高值质控物，20参数	Content Inhalt Contenido Contenudo Contenu Indhold Περιεχόμενο Innehåll Conteúdo Zawartość opalpwania Innehold Sisu Obsah 容量	Control Kontrolle Control Controllo Contrôle Kontrol Πρότυπο ελέγχου Kontroll Controlo Materiał kontrolny Kontroll Kontroll Kontrola 质控物
	CONTROL N 20	CONTROL L 20	REF	CAL
GB DE ES IT FR DK GR SE PO PL NO EST CZ CN	Normal control, 20 parameters Normal Kontrolle, 20 Parameter Control normal, 20 parámetros Controllo normale, 20 parametri Contrôle normale, 20 paramètres Normal Kontrol, 20 parametrer Πρότυπο ελέγχου Κανονικό, 20 Παράμετρος Normal kontroll, 20 parametrar Controlo normal, 20 parâmetros Poziomie normalnym kontrolny, 20-parametrowy Kontroll; 20 parametere, normal Normaalne kontroll, 20 parameetrit Normální kontrola, 20 parametrů 中值质控物，20参数	Low control, 20 parameters Nierig Kontrolle, 20 Parameter Control bajo, 20 parámetros Controllo basso, 20 parametri Contrôle bas, 20 paramètres Lav Kontrol, 20 parametrer Πρότυπο ελέγχου Χαμηλό, 20 Παράμετρος Låg kontroll, 20 parametrar Controlo baixo, 20 parâmetros Poziomie niskim kontrolny, 20-parametrowy Kontroll; 20 parametere, lav Madal kontroll, 20 parameetrit Nízká kontrola, 20 parametrů 低值质控物，20参数	Catalogue number Bestellnummer Número de catálogo Numero di catalogo Référence du catalogue Katalognummer Αριθμός καταλόγου Katalognummer Referência de catálogo Numer Katalogowy Katalog-/referansenr. Kataloogi number Katalogové číslo 目录号	Calibrator Kalibrator Calibrador Calibratore Calibrateur Kalibrator Διάλυμα Βαθμονόμησης Kalibrator Calibrador Kalibrator Kalibrator Kalibraator Kalibrátor 校准物
GB DE ES IT FR DK GR SE PO PL NO EST CZ CN	The sampling needle may cause injury Die Probenahme Nadel kann zu Verletzungen führen La aguja de muestreo puede causar lesiones L'ago di campionamento può causare lesioni L'aiguille de prélèvement peut entraîner des blessures Prøveudtagningen nålen kan forårsage skade Η δειγματοληψία βελόνα μπορεί να προκαλέσει τραυματισμό Den provtagning nål kan orsaka skada A agulha de amostragem pode causar lesões Igły do pobierania próbek może spowodować szkody Det prøvetaking nålen kan forårsake skade Proovivõtu nõela võib põhjustada vigastusi Odběr vzorků jehlou může způsobit zranění 抽樣針可能造成傷害	Radiation of laser apparatus Strahlung der Laser-Geräte La radiación del láser aparatos Radiazione di apparecchi laser Rayonnement de laser appareils Stråling af laser apparater Ακτινοβολία του λέιζερ συσκευών Strålning av laser apparater Radiação laser de aparelhos Promieniowania laserowego urządzenia Stråling av laser apparater Kiirgus laseriga seadmed Záření laserového přístroje 輻射激光儀器		

Figure 1.7 IVD Symbol Table

Section 2: Installation

Section Overview

Introduction This section describes how to unpack and install the Quintus instrument.

Contents This section contains the following topics:

Topic	See Page
Unpacking / Operating Placement and Environment	10
Installation Checklist	12
Removing Safety Card from Shear Valve	12
Reagent Installation and Instrument Initialization	13
Connecting the Autoloader (optional)	16
Initial Setup	17
Analyzer Cable, Interface, and Printer Connections	19
Power Supply	20

2.1 Unpacking / Operating Placement & Environment

Description The instrument is packed in a specifically designed protective box.

Visual Checking Check the box for physical damage. If damaged notify your carrier immediately.

Included Material

- Instrument
- User's Manual
- Quick Reference Guide
- Sample adapter
- Reagent tube kit (in a plastic bag, with special caps)
- Power cord
- Barcode reader
- Waste container
- Maintenance kit (Shipment tubing; empty vial for Cleaner)
- Installation form
- Declaration of Conformity

Optional Material

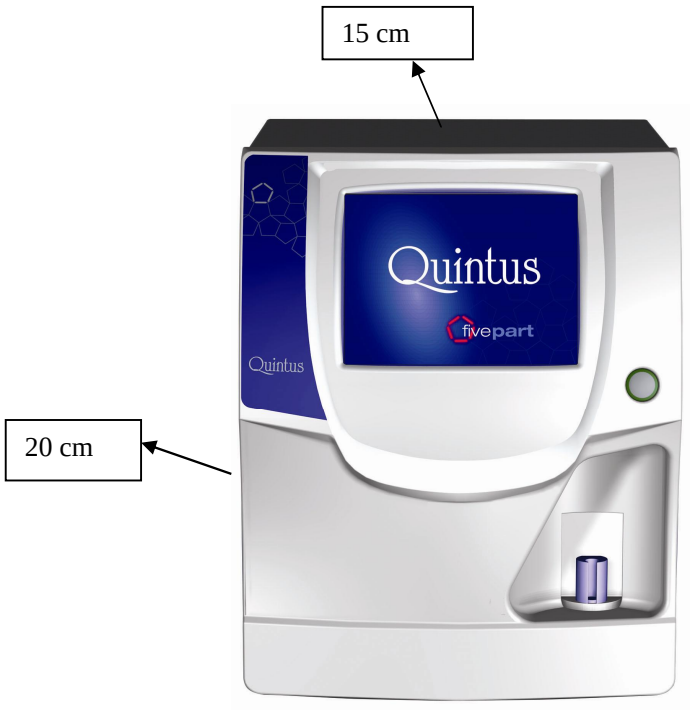
- Printer
- Autoloader (Autoloader unit, sample tray, and 10 sample racks)
- External Keyboard

Important The following procedures must be followed exactly. Boule has no responsibility in case of faulty or erroneous installation.

Installation/ Operating Placement

The instrument should be placed in a laboratory environment according to the guidelines below:

- Place the instrument on a clean horizontal surface.
- The analyzer weighs 35 kg (77 lbs); two persons are needed to lift analyzer.
- Avoid lifting the analyzer by the front cover.
- Avoid exposure to sunlight.
- Make sure the instrument has access to proper ventilation. The instrument should have at least 20 cm (8 inches) of space on both sides and above it.
- Place the rear of the instrument so it has at least 15 cm (6 inches) of free space behind it.
- Clearance in front of the Quintus to be able to open the front panel and comfortably reach the analyzer.



Installation/ Operating Environment

- Indoor Use
- Temperature +15 to +30 ºC (+59 to +86 ºF)
- Optimal operating temperature +25 ºC (+77 ºF)
- Humidity < 80% Relative
- Grounded main supply

Important

- Operating the instrument in an environment over +32 °C (+ 90°F) increases service needs, as well as degradation of sample specimen.
- Operation at an altitude over 3000 meters (9000 ft) is not recommended
- The analyzer should not be placed near potentially interfering devices capable of emitting radio frequencies (e.g. radio or television receiver, radars, centrifuge, X-ray devices, fans, etc.)
- Allow 15 minutes from power on for the analyzer and its internal components to reach optimal operating temperature range

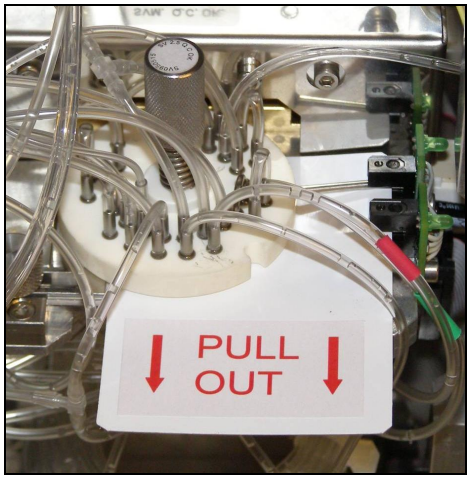
2.2 Installation Checklist

Description Follow the quick Installation Checklist and Installation Menu step by step for best installation results. For more detail on each step refer to Sections 2.3 – 2.8.

Installation Checklist	
☐	Complete Unpacking / Operating Placement and Environment instructions in Section 2.1.
☐	Remove the safety card from shear valve and tighten shear valve.
☐	Connect the waste tubes to the analyzer and plumb to waste container or drain.
☐	Connect the reagent tubing to corresponding, color-coded reagent ports.
☐	Connect the other end of reagent tubing to cap and place in correct reagent container.
☐	Connect the power to the back of the analyzer, but do not plug it into an electrical socket.
☐	Connect the barcode reader to the back of the analyzer.
☐	If using Autoloader, push autoloader into the Quintus until the clamp is locked.
☐	Plug the power cord into the electrical socket and turn on analyzer at main power switch.
☐	Toggle on Standby switch to initialize the system.
☐	Scan in reagent barcodes.
☐	Press NEW SAMPLE button to perform self-test and to perform Fill process.
☐	Setup up date/time and language.
☐	To connect the analyzer to peripherals, such as the printer or a computer, see Section 2.7.

2.3 Removing Safety Card from Shear Valve

Description In order to prevent damage of the shear valve during transportation, a protective plastic card is placed between the ceramic disks of the shear valve. Before using the analyzer, this card must be removed.

Step	Action
1	Open the cover of the analyzer and locate the white plastic card in shear valve.
2	Pull out the card, in one quick motion.
3	Check and tighten the locking screw of the shear valve.
	 Figure 2.2
Note	For more information on cleaning and assembling the shear valve see Section 9.

2.4 Reagent Installation and Instrument Initialization

Description

First start-up is special, because the Quintus arrives to your laboratory drained, without reagents. Prior to analyzing samples, it is necessary to enter in the reagent barcodes and fill the analyzer with reagents.

Supported Reagents

- The reagents for the instrument are delivered in cube formed boxes with plastic caps.
- Hemolyzing reagent, Isotonic diluent, and Stop solution, hereafter referred to as Lyse, Diluent, and Stopper. (Specifically designed by Boule for the Quintus system.)

Placement of reagent containers

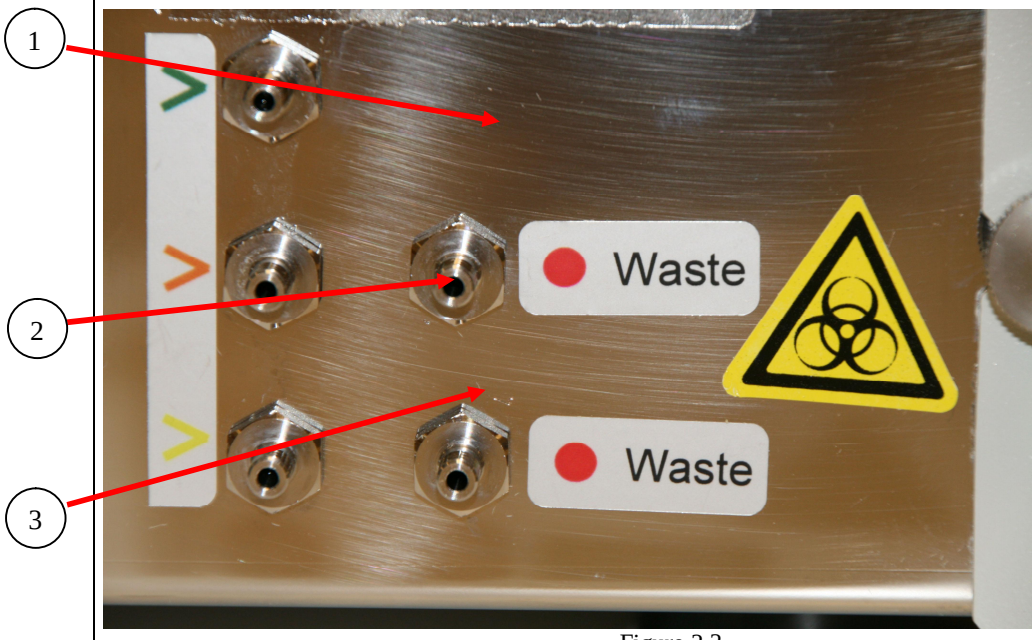
- It is recommended that all reagents are placed at the instrument level or below.
- The analyzer has the capability to aspirate reagents from 1.2 meters (4 feet) below the analyzer.

Note

- Placing the reagent containers above the instrument level could cause system flow issue and is not recommended.

Connecting Reagent Containers

This section describes how to connect the reagent containers for use.

Step	Action
1	Connect the Diluent tubing (green) to the diluent input port.
2	Connect the Stopper tubing (orange) to the stopper input port.
3	Connect the Lyse tubing (yellow) to the lyse input port.
	 Figure 2.3
4	Connect the Diluent tubing to the cap with the longer tubing, and the Lyse and Stopper tubing to the two caps with shorter tubing.
5	Insert reagent tubing into corresponding reagent container and tighten cap.

Waste

Connect the waste tubes to the analyzer. Place the other end of the waste tube directly into the drainage system or into a waste container, following local regulations. See Section 9.9 for Disposal information.

Caution

The end of the waste tubing must be at a lower level than the instrument itself. Not following this may lead to improper instrument functions and/or waste liquid flowing backwards into the instrument.

Mandatory Action

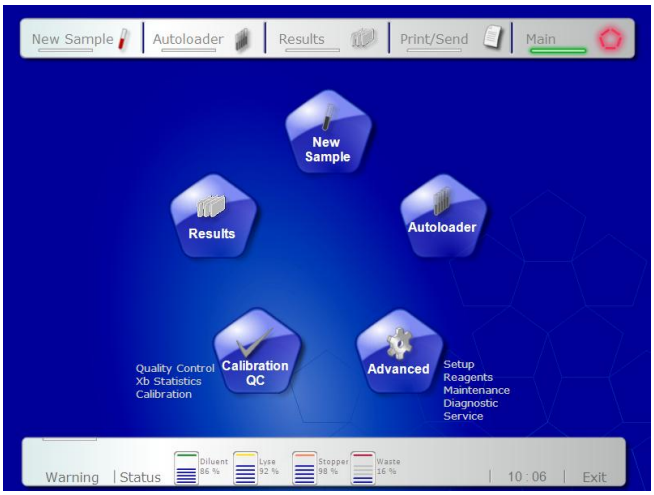
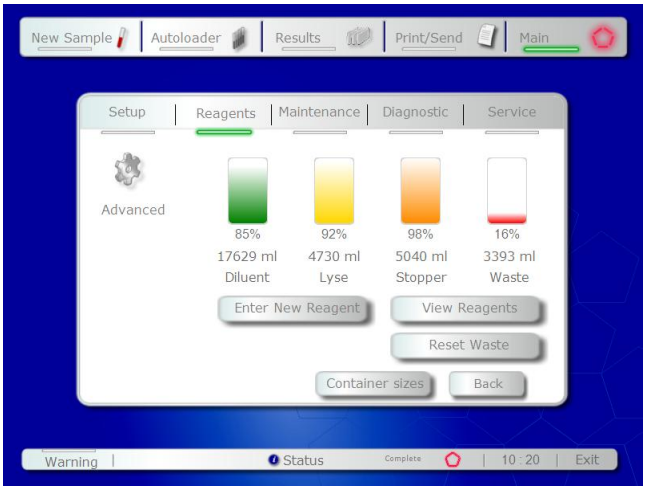
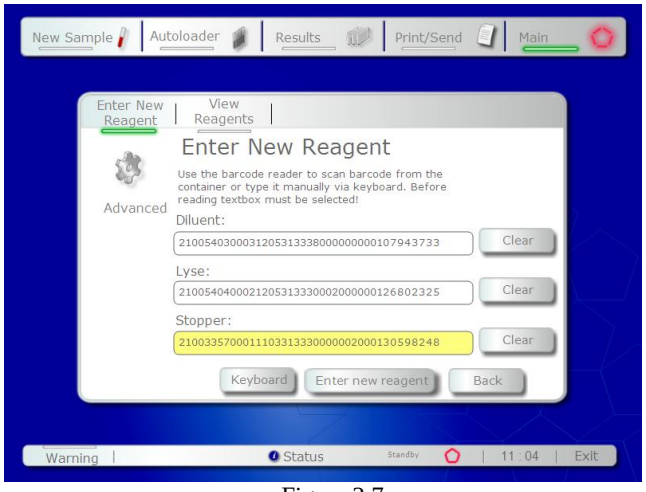
Always use protective gloves when working with the waste container and the waste tubing.

Initialize System

To power on and initialize the system, perform the following:

Step	Action
1	Plug in analyzer and turn the main power switch to ON. (This is the small switch near the power cord.)
2	Facing the analyzer, flip the Standby switch in the rear, upper-right corner of the unit by the serial number label.
Note	• The computer inside the analyzer needs a few minutes to start up and initialize the operating software. • The Quintus software starts automatically and puts you in the main menu. This menu allows access to analyzer setup, and you can also start operation.
	 Figure 2.4

Reagent Barcode Entry To enter reagent barcode, perform the following steps:

Step	Action
1	Select ADVANCED menu.
	 Figure 2.5
2	Press [REAGENTS] and then press [ENTER NEW REAGENTS].
	 Figure 2.6
3	Press the text box under the reagent you will scan in (it will highlight in yellow when activated) and then scan in the barcode from the corresponding reagent container. Repeat for all reagents.
	 Figure 2.7
4	Press [ENTER NEW REAGENT] to save.

Fill system

To fill the system for the first time, press [NEW SAMPLE] quick link at the top of the screen. During this first initialization, the analyzer performs a number of functions:

- Starts up and performs a self-test on the hardware, electronics, and the software in the system
- Fills up the analyzer with reagents
- Performs an automatic background count

Background count

Even though maximum precaution and quality measures are taken in the factory, transportation and extended storage can cause higher background counts for the first few backgrounds analyses. Therefore it may be necessary to run 5-10 initial background measurements to rinse the tubing.

Note

- The user must [ACCEPT] the background measurement before real samples can be analyzed.

2.5 Connecting the Autoloader (optional)

Description

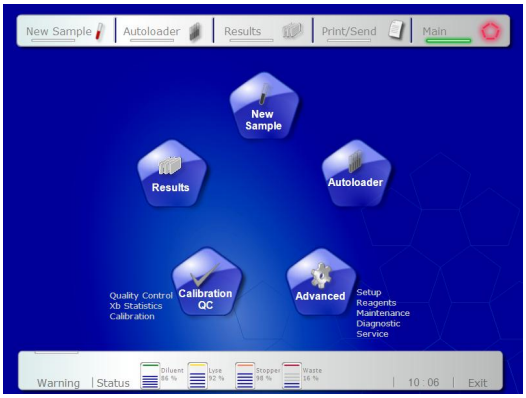
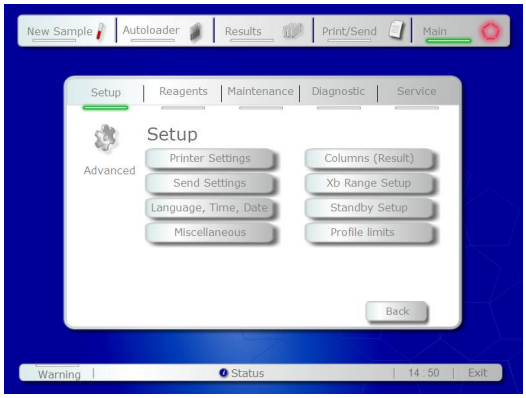
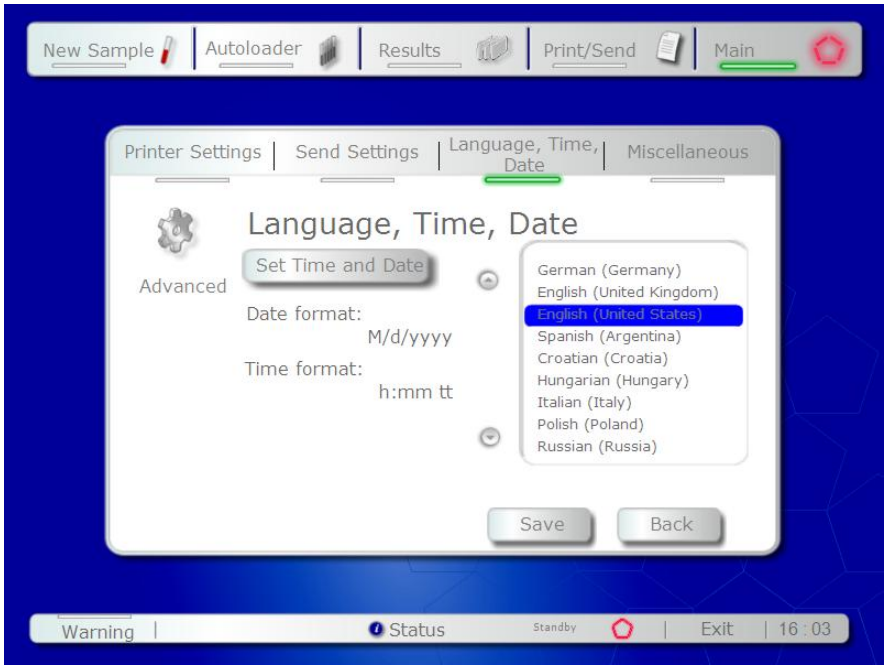
If the optional Autoloader has been purchased with the system, then connect it to the analyzer prior to powering on either of the units.

Step	Action
1	To connect the Autoloader to the analyzer, simply slide in the unit into opening on right-hand side of the analyzer until the clamp locks into place.
	Figure 2.8
Note	If the analyzer and autoloader were purchased separately, the user may need to remove the secondary cover plate and attach the frame to the side panel. See assembly instructions included in the Autoloader packaging for further instruction.

2.6 Initial Setup

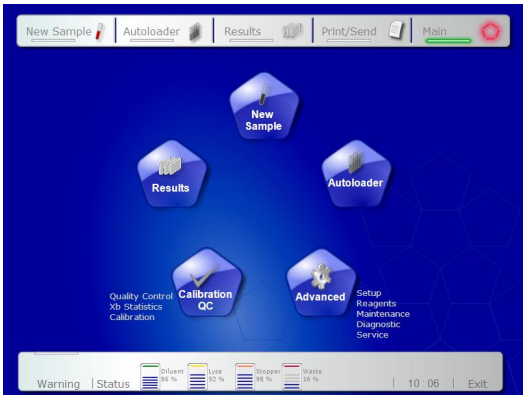
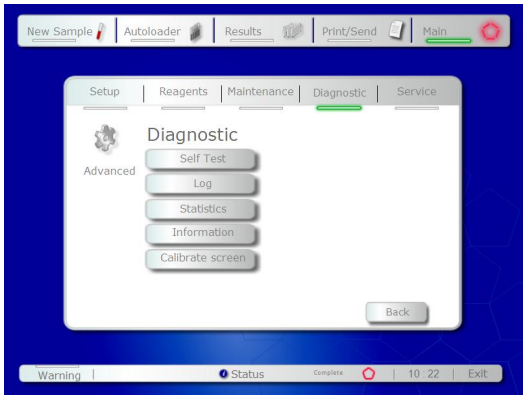
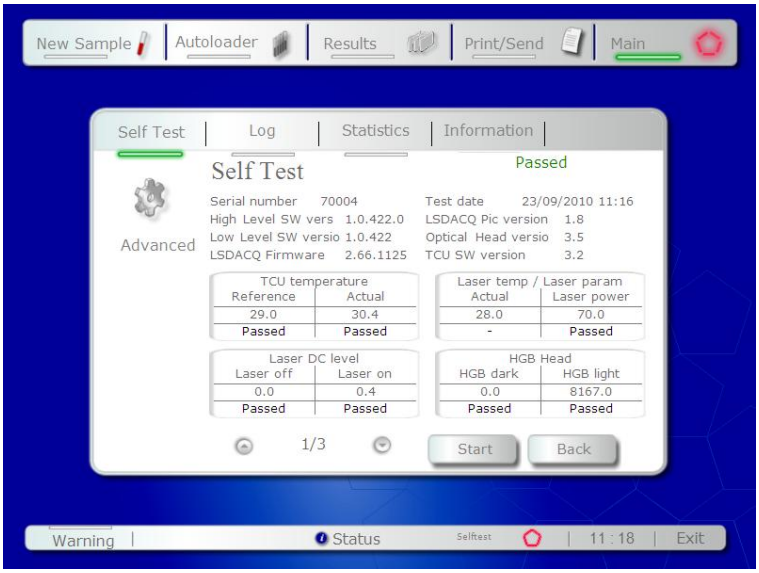
Initial Setup

Initial setup of the instrument, except date and time, has been factory set to default values for the average Boule users. However, other user definable formats may be preferred, details are provided below and in Section 4.

Step	Action
1	To set the date and time select [ADVANCED] then [SETUP] and then [LANGUAGE, DATE, TIME].
	 Figure 2.9  Figure 2.10
2	Select [SET TIME AND DATE] button
	 Figure 2.11
3	Adjust the time and date, if necessary, select [OK] to exit screen and [SAVE] to accept new entry.
4	To adjust the language, scroll to the language of choice, highlight and [SAVE] to accept the change.

Print All Settings

After initial setup, it is recommended to print all analyzer settings and keep them for personal records.

Step	Action
1	The first step is to run a Self Test. Select [ADVANCED] from Main menu, then [DIAGNOSTICS], and then [SELF TEST].
	 Figure 2.12  Figure 2.13
Note	Prior to running the Self Test, it is recommended to let the analyzer warm-up for 15 minutes and background count must have been accepted.
2	Select [START] button. This function will take about a minute.
	 Figure 2.14
3	Once Self Test is complete, select [PRINT/SEND] tab. Save this printout for personal records.

Factory Calibration

All sample analysis modes (open tube, cap piercing, and autoloader) are factory calibrated. However, calibration should always be checked upon installation. See Section 8 for more details.

2.7 Analyzer Cable, Interface, and Printer Connections

Description

All connections are located on the rear panel of the instrument. The connections available are as stated below:

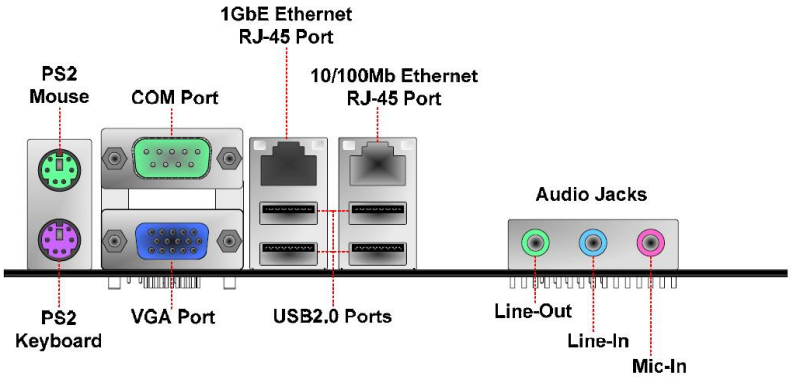


Figure 2.15

Port	Function
PS2 Mouse port	Connects optional mouse to analyzer
PS2 Keyboard port	Connects optional external keyboard to analyzer.
Serial COM port	Connects hospital data collection system (3.1 protocol) to analyzer.
VGA port	Connects VGA monitor to analyzer – **for service purposes only.**
RJ-45 LAN ports	Connects hospital data collection system (10/100Mb Ethernet for HL7 protocol) to analyzer.
USB 2.0 ports	Connects USB devices, such as printer and barcode reader to analyzer. (4 ports)
Audio jacks	Line-out, Line-in and MIC-in (Horizontal, Smart 5.1 supported) - **not used.**

Peripheral Device Setup

The Quintus Windows® XP® * Embedded recognizes most of the peripherals such as keyboards, mouse, and memory sticks without any additional installation process.

*Registered trade mark

Step	Action
1	Shut down the analyzer.
2	Connect the desired peripheral device.
3	Power up the Quintus.
4	After initialization of the system, the peripheral device should be installed automatically.
Note	If your device requires any additional installation steps, then service level action is required.

Printer Installation

The printer required additional installation steps. Please allow an authorized distributor or service technician to perform the installation.

- Any Windows® XP® Embedded compatible printer can be installed.
- The printer is connected to the rear of the instrument with USB printer cable. (Printer is not manufactured by Boule.)

Computer and LIS Setup

For setting up a computer link, please see Section 4.

2.8 Power Supply

Main supply environment

The main power supply is located internally and designed to be operated indoors. The power supply is safe for transient voltage as defined in IEC 801-4.

Warning

Electrical shock hazard.

- The instrument must only be connected to a grounded mains supply. Violating this might result in injuries and/or loss of life and/or erroneous parameter results.

Handling high transient voltage

If high voltage transients are expected on the main supply, please follow the recommendations below.

Warning

Electrical shock hazard.

- Installation of external electrical equipment such as CVT must only be carried out by authorized service engineers. Violating this might result in injuries and/or loss of life and/or erroneous parameter results.

In case of	Symptom	Solution
High transient voltage above 15%	-High background counts on RBC, PLT or WBC. -Defective instrument.	A CVT (magnetic stabilizer) should be implemented to keep the instrument from being damaged. (In general, avoid the use of an UPS.)

Guidelines

Guidelines are given in the Service Manual, “Installation auxiliary devices” section. Contact your authorized distributor in such a case.

Power interruptions

In case of an abrupt power loss there will be no damage done to the instrument. Calibration constants and other parameters necessary for operation are protected against main supply loss.

Before connecting

In order to run the instrument, the frequency and main voltage needs to correspond to user’s power outlet.

- Locate the serial number plate on the rear of analyzer and check that the main voltage and frequency corresponds to local main outlet.
- If voltage and/or frequency does not correspond, then contact your authorized distributor

Connecting Power Cable

Insert power cable into the instrument’s main power inlet and connect it to the main power supply.

- Only the power cord supplied with the analyzer should be used. Avoid using extension cords.

Section 3: General Overview

Section Overview

Introduction This section contains general information about the instrument and optional accessories.

Contents This section contains the following topics:

Topic	See Page
General Instrument Overview	21
System Menu	22
Sample Volume, Throughput, and Parameters	24

3.1 General Instrument Overview

Instrument Overview

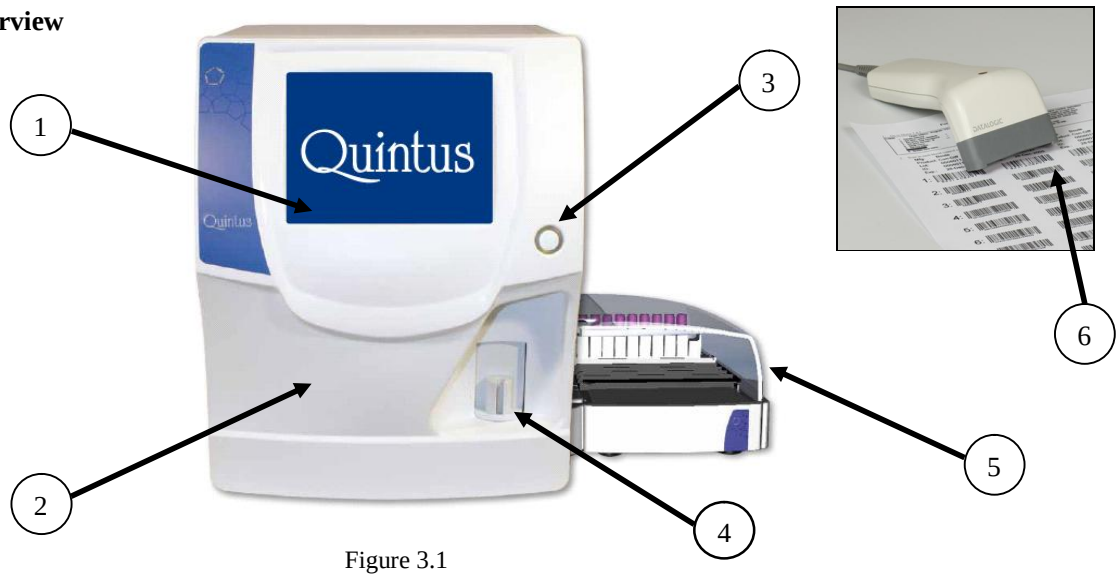
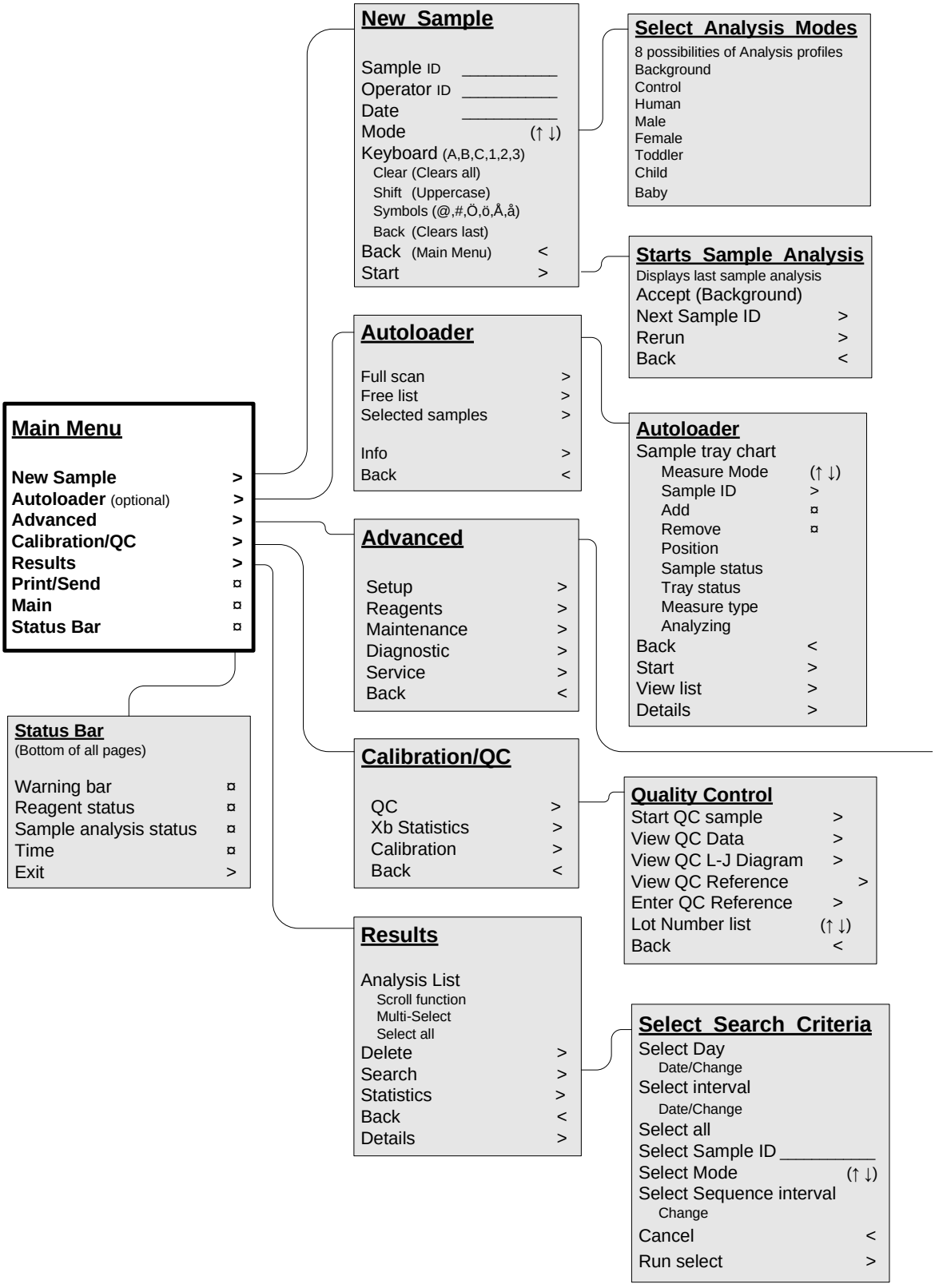


Figure 3.1

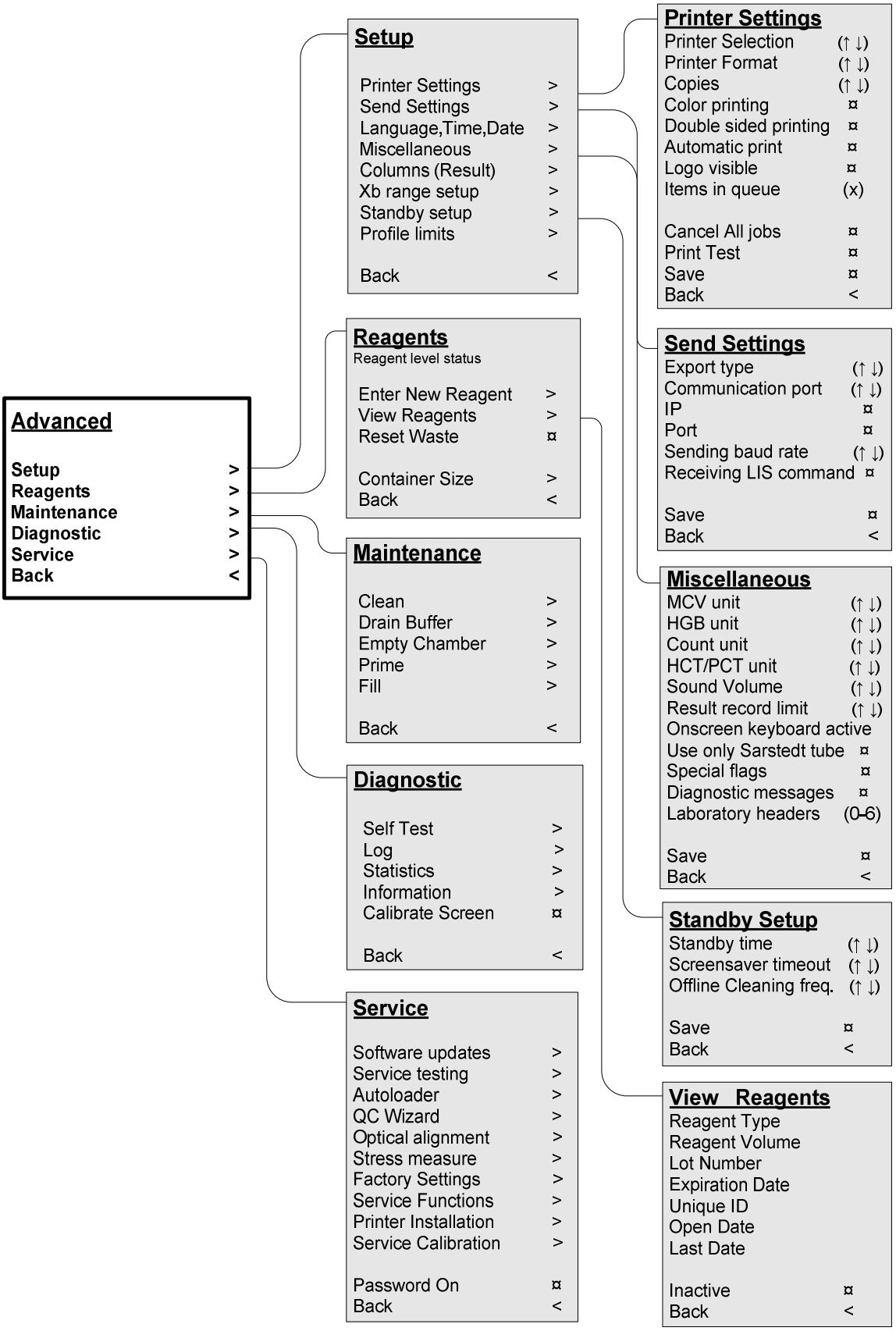
Part	Function
1. Display	This is the main user interface of the Quintus. User interactions and data input happen using this screen.
2. Front Panel	This is the cover for the main fluidic element like the shear valve, sampling needle, syringes, etc. It can be easily opened if any maintenance is necessary.
3. Start Button	To start the manual measurement you can push the START button in the front panel. The color of the START button identifies the status of the Quintus. The green color means Quintus is ready to measure. The red color means Quintus is engaged in measurement. The orange color means Quintus is in the stand by state.
4. Sample Rotor	The needle takes a manual sample from the tube inserted in the sample holder. The sample rotor turns into the Quintus covering the sample needle from unintended touch.
5. Autoloader	Enables consecutive samples to be analyzed automatically.
6. Barcode Reader	Barcode reader enables user to quickly enter patient, control, and reagent pack identifications, and utilize the QC program.

3.2 Menu Structure

Flowchart 3.1 Main Menu Structure



Flowchart 3.2 Advanced Menu Structure



3.3 Sample Volume, Throughput, and Parameters

Description The Quintus is a fully automated cell counter reporting up to 24 parameters.

Sample volume ~100 µl

Throughput ≥ 60 samples per hour

24 Parameters See list of parameters below:

Leukocyte parameters	
WBC	Total White Blood Cell Count
LYM%	Lymphocytes percentage
LYM#	Lymphocytes (absolute)
MONO%	Monocytes percentage
MONO#	Monocytes (absolute)
GRAN%	Granulocytes percentage
GRAN#	Granulocytes (absolute)
EOS%	Eosinophil percentage
EOS#	Eosinophil (absolute)
BASO%	Basophil percentage
BASO#	Basophil (absolute)

Erythrocyte parameters	
RBC	Total Red Blood Cell Count
HGB	Hemoglobin Concentration
HCT	Hematocrit
MCV	Mean Cell Volume of RBCs
MCH	Mean Cell Hemoglobin
MCHC	Mean Cell Hemoglobin Concentration
RDW%	Red Blood Cells distribution width percentage
RDWa	Red Blood Cells distribution width (absolute)

Thrombocyte parameters	
PLT	Total Platelet Count
MPV	Mean Platelet Volume
PDW	Platelet Distribution Width
PCT	Platelet Crit
LPCR	Large Platelet Concentration Ratio

Section 4: Instrument Setup

Section Overview

Introduction

This section covers the initial configuration needed to customize the instrument settings.

Contents

This section contains the following topics:

Topic	See Page
Main Menu and Touch Screen	25
Advanced Setup	27
Printer Settings	27
Send Settings	28
Language, Time, Date Settings	29
Miscellaneous Settings	30
Result Column Settings	31
Xb Range Settings	32
Standby Settings	32
Profile Limits Settings	33

4.1 Main Menu and Touch Screen

Main Menu

The Main menu will be displayed upon initialization.

- From this main screen all other menus can be accessed.
- The Main menu is divided up into three main sections:
    1. Quick links to main functions (upper part)
    2. Interactive display area (middle section)
    3. Status display (bottom section)

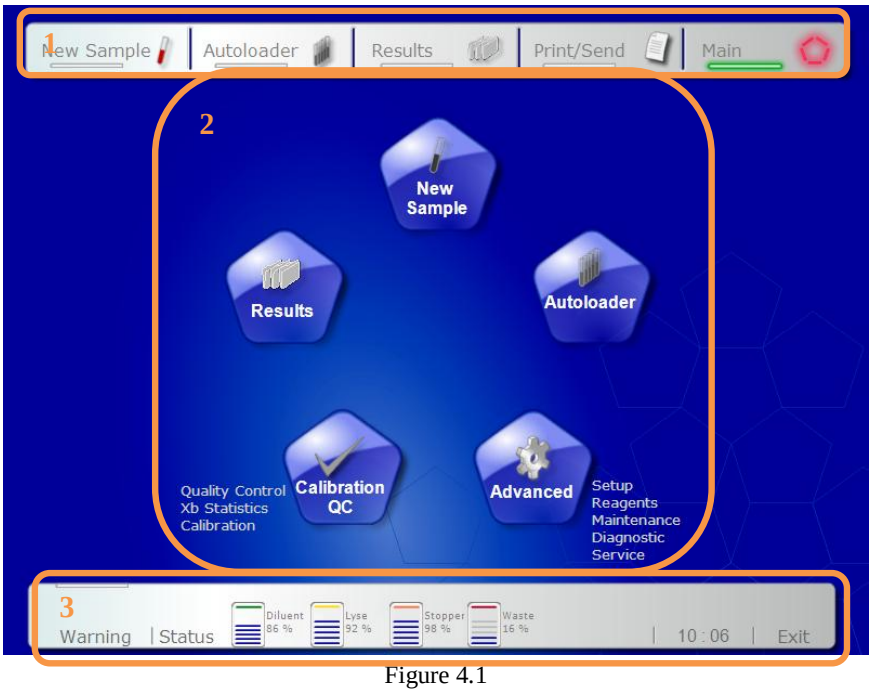


Figure 4.1

Quick links

This upper section of the display is visible during all operations providing a one-touch entry for the following:

- Start a manual or autoloader measurement
- Open the measurement database (RESULTS) or Main menu
- Initiate printing and/or sending of results

Interactive display

The middle section is used to display function or menu specific information, results, and all the dialogs that contain relevant information to the active operation mode.

- Icons are arranged in a pentagon design and the following sub-menus can be opened (See Section 3.2 for detailed menu structure) :
    - New Sample
    - Results
    - Calibration/QC
    - Advanced
    - Autoloader

Status display

The status display shows the following:

- Estimated fullness of the reagent and waste container
- Warning messages
- The status and progress of the active operation of the analyzer
- The actual time
- Printer status
- Exit

Simply press anywhere on the status bar to minimize or maximize it.

Using the Touch Screen

- The touch screen display used in the Quintus analyzer is selected for reliability, endurance and compatibility with medical, laboratory environment.
- The touchable items on the display are designed to be big enough to tap with finger. However in some cases you may find the usage of a tapping tool useful.
    - the blunt end of a pen or pencil
    - a plastic ‘stylus’ used with PDA devices

Important

- Do not use sharp or heavy objects to operate the touch screen.
- Though the surface material is moderately resistive to liquids, avoid touching the screen with wet fingers or allowing liquids to come into contact with the screen.

Using an external mouse

An external (PS2/ USB) mouse can also be used, giving the same functionality as the touch screen. By moving the mouse, navigate the mouse pointer over the desired item. Instead of tapping the touch screen press the LEFT mouse button to activate the function. See Section 2.7 Peripheral Device Setup for further instruction on installation.

Using an external keyboard

An external (PS2/ USB) keyboard can also be used giving the same functionality as the virtual keypads on the display. This is especially useful for quick data entry of the Sample ID if barcodes are not being used. See Section 2.7 Peripheral Device Setup for further instruction on installation.

4.2 Advanced Setup

Description

Initial advanced setup of the analyzer, has been factory set to default values. However, other user definable formats may be preferred, details on how to setup these preferences and more detail on how to install and configure external components such as barcode readers, printers, data communication, etc. are provided below.

Setup Menu

In the SETUP menu you can change following settings:

- PRINTER SETTINGS
- SEND SETTINGS
- LANGUAGE, TIME, DATE
- MISCELLANEOUS
- COLUMNS (RESULT)
- XB RANGE SETUP
- STANDBY SETUP
- PROFILE LIMITS

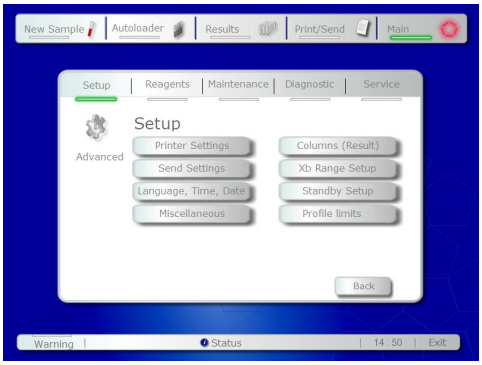


Figure 4.2

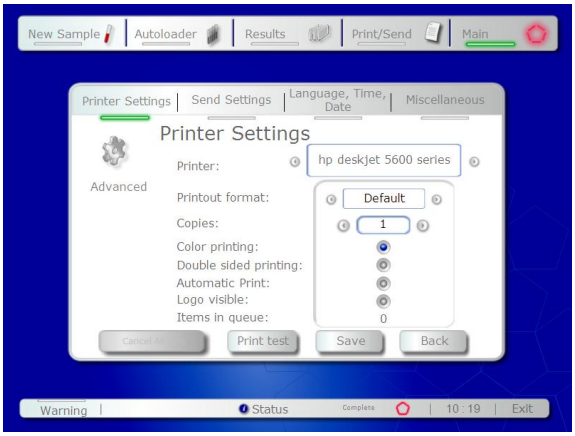
Important

- All changes to settings are made effective by using the [SAVE] function.
- To discard the changes and return to the Setup menu select the [BACK] button.

4.3 Printer Settings

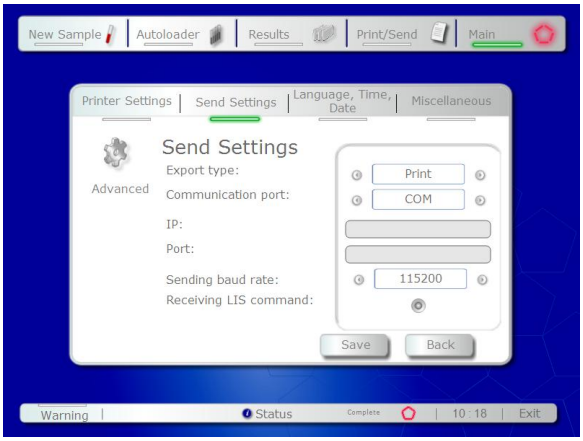
Printer Settings To select options for printing results.

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [PRINTER SETTINGS] to enter the Printer setup.
3	Printer: Select the printer to use from the printer list using the scroll buttons.
4	Printout format: Select between different layouts for the printout.
5	Copies: Use the scroll buttons to select the number of copies printed when user presses [PRINT/SEND] tab.
6	Color printing: Enable/ disable color printing. (The checkbox is available if the printer driver supports the feature.)
7	Double sided printing: Enable/ disable double sided printing. (The checkbox is available if the printer driver supports the feature.)

Step	Action
	 Figure 4.3
8	**Automatic print**: When selected allows automatic printing with every sample analyzed. (This is independent of Export type setting.)
9	**Logo visible**: When selected allows logo to be printed on every printout.
10	**Items in queue**: User can view the number of pending printer jobs
11	**Cancel all jobs**: Press to cancel the remaining printouts pending in the queue.
12	**Print test**: Press button to test printer functionality and connectivity
Note	To install printer see Section 2.7.

4.4 Send Settings

Serial Setup To select options for sending results and data follow instruction below:

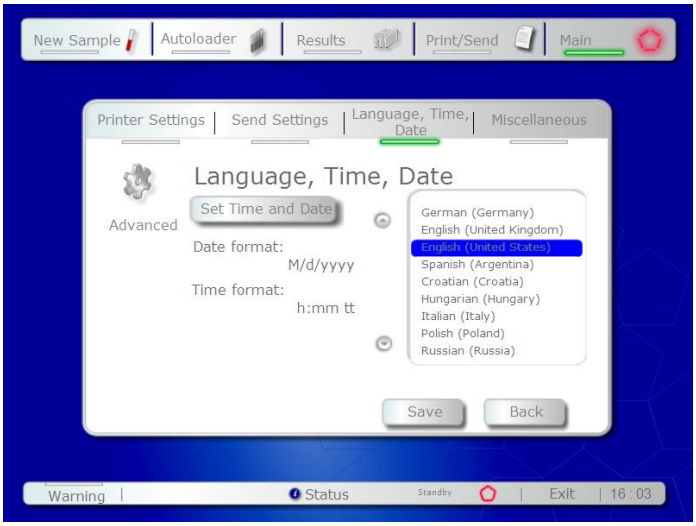
Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [SEND SETTINGS] to enter the Send setup.
	 Figure 4.4
3	**Export type**: This function allows the user to set the default Export type. This export type will function when the [PRINT/SEND] button is pressed. • Printer • Send to LIS – Enables/ disables the IP based LIS/ HL7 protocol • To text file • To binary file • To raw data

Step	Action
4	**Communication port**: Select either COM or Ethernet if using this function. Note: For Communication port activation to function correctly user must have a PC application that can receive and process reports.
5	**IP**: If applicable, enter the IP address of the LIS/HL7 host. (Available only if the LIS checkbox is selected.)
6	**Port**: If applicable, enter the port number of the listening port on the LIS/HL7 host. (Available only if the LIS checkbox is selected.)
7	**Sending port baud rate**: Select either 9600 or 115200 baud to determine the speed of the serial communication to/from the host system if using this function. Note: If the cable is longer than 5 m (15 feet) then select 9600 baud.
8	**Receiving LIS command:** Select to allow Remote worklist communication to be received from the host system into the New Sample or Autoloader Free-list mode. See Doc. 14154 on website for more information.

4.5 Language, Time, Date Settings

Language, Time, Date Setup

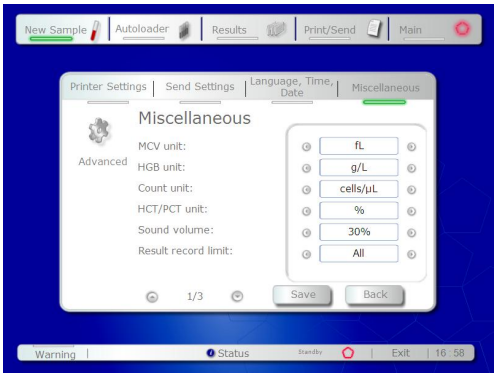
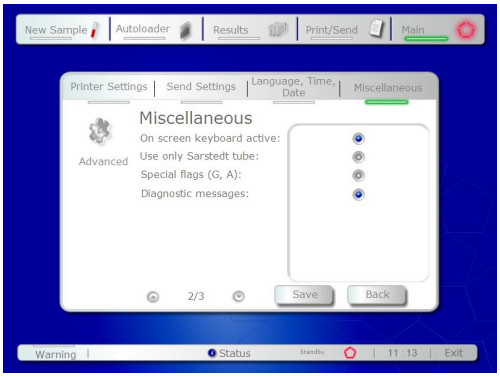
To select options for setting the date, time and language follow instructions below:

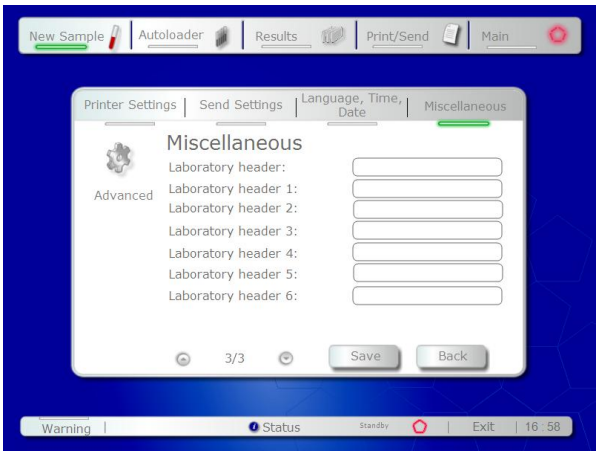
Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [LANGUAGE, TIME, DATE] to enter setup menu.
3	Select [SET TIME AND DATE] button
	 Figure 4.5
3	Adjust the time and date, if necessary, select [OK] to exit screen and [SAVE] to accept new entry.
4	To adjust the language, scroll to the language of choice, highlight and [SAVE] to accept the change.

4.6 Miscellaneous Settings

Miscellaneous Setup

To select options for setting units, de-activation of on screen keyboard, activation of Sarstedt tube for analysis, volume, o follow instructions below:

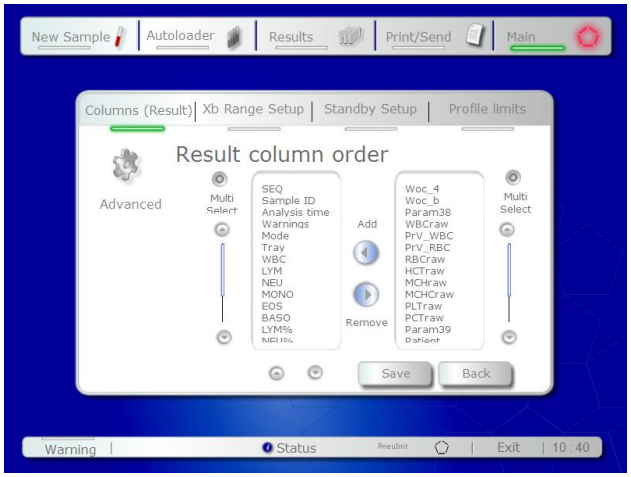
Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [MISCELLANEOUS] to enter the Miscellaneous setup. Use scroll buttons to scroll to second and third pages of this setup menu.
	 Figure 4.6  Figure 4.7
3	To change units use scroll bars to select preference: **Parameter** / **Units** **MCV unit**: fL, µm³ **HGB unit**: g/L, g/dL, mmol/L **Count unit**: cells/ µL, cells/L **HCT/PCT unit**: Absolute, %
4	**Sound volume**: Use scroll buttons to change the volume of the audio feedback. • Use the "0%" setting to turn off the audio feedbacks
5	**Result record limit**: Use the scroll buttons to choose either ALL or LAST MONTH • All – All the previous measurements are visible under RESULTS • Last month - Only results from the last 30 days are visible under RESULTS
6	**On screen keyboard active**: Select this function to enable or disable the touch screen and use an external keyboard for Sample ID entry. Note: Do not disable if there is no external keyboard connected
7	**Use only Sarstedt tube:** Select this function if using Sarstedt® Monovette® tubes for manual measurements. Note: This is not applicable for the Autoloader, it is able to identify sample tube type prior to analysis.
⚠ **Caution**	**If switching between Sarstedt tubes and other types of sample tubes user must enable/disable this function or damage could occur to the sampling needle.**
8	**Diagnostic Messages**: Select this function to enable or disable the messages associated with Out-of-Range Indicators, see Section 10.1. Note: It is recommended that this function is enabled.

Step	Action
	 Figure 4.8
	Laboratory header: Use this function to enter a laboratory header on the top of the printout. • 7 lines are available for entry, each line can hold up to 42 characters.

4.7 Result Column Settings

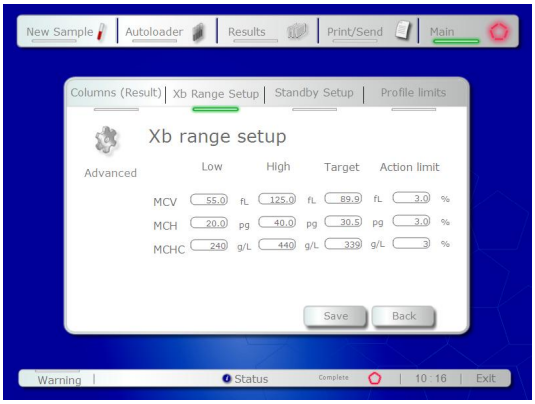
Setting Result Columns

This section allows the user to select which parameter shall be displayed and in which order under the Results tab.

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [COLUMNS (RESULT)] to enter setup menu.
	 Figure 4.9
3	To add a parameter to the Results list, select the parameter from the right-hand column box and select the [ADD] button.
4	To remove a parameter to the Results list, select the parameter from the left-hand column box and select the [REMOVE] button.
Note	To add or remove multiple parameters at once to/from the Results list press the Multi-Select buttons above corresponding column box. • To disable the Multi-Select button simply press the button again.
5	To change the order of parameter in the Results list, select the parameter in the left-hand column box and use the UP and DOWN arrows, below the box, to move the parameter to the desired position in the list.

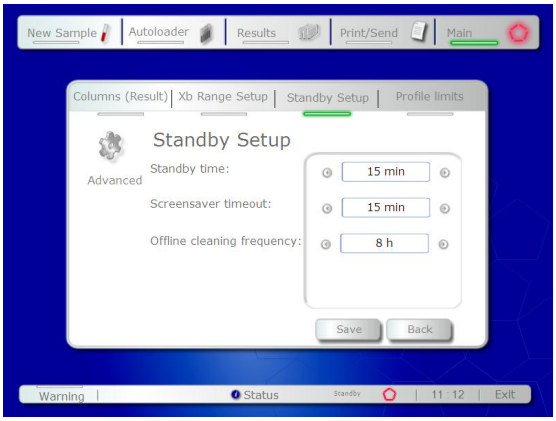
4.8 Xb Range Settings

Xb Range Setup This section allows the user to set the low and high Xb ranges, target value, and action limits.

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [XB RANGE SETUP] to enter setup menu.
	 Figure 4.10
3	To change the Xb low or high limits, select the range box and type in new range.
4	To change the Xb target value, select the target value box and type in new target value.
5	To change the Xb Action limit, select the limit box and type in new limit.

4.9 Standby Settings

Standby Setup This section allows the user to set the standby time, screensaver timeout, and offline cleaning frequency.

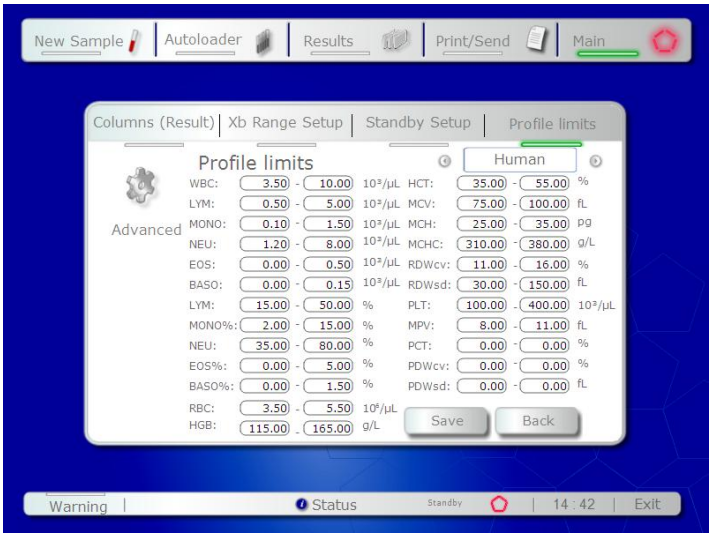
Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [STANDBY SETUP] to enter setup menu.
	 Figure 4.11
3	Standby time: Use scroll buttons to change the how long the analyzer should wait before leaving the ready state and preparing for inactive operation. • Choose between 3, 5, 10, and 15 minutes • Recommended setup time is 15 minutes

Step	Action
Note	The Standby time is activated after a background, control, or sample analysis.
4	**Screensaver time**: Use scroll buttons to change the how long the analyzer should wait before the screensaver function is activated. • Choose between 3, 5, 10, 15, 30, and 60 minutes • Recommended setup time is 15 minutes
Note	To activate the display simply touch the screen.
5	**Overnight Clean**: Use scroll buttons to change how long the analyzer should wait before running the overnight cleaning. • When this function is activated, the software will perform a minor fluidic operation to make sure that there are fresh reagents in measurement critical sections of the tubing system. • Choose between 0, 4, 8, 12, and 24 hours • Recommended setup time is 8 hours
Note	0 hour selection means no cleaning cycle will be performed

4.10 Profile Limits Settings

Profile Limits Setup

Indicative normal ranges (profile limits) are provided in this instrument. It is recommended to establish local reference ranges (normal ranges) for your laboratory. (See CLSI standard C28-A2 for guidance on how to establish these ranges and examples of normal ranges in the reference documents listed at the end of this section.)

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [PROFILE LIMITS] to enter setup menu.
	 Figure 4.12
	To change the low or high profile limits, select the limits box and type in new limit.

Normal Range References

1. Cheng C, Chan J, Cembrowski G, van Assendelft O. Complete Blood Count Reference Interval Diagrams Derived from NHANES III: Stratification by Age, Sex, and Race *Laboratory Hematology* 10:42-53
2. Nordin G, et al. A multicentre study of reference intervals for haemoglobin, basic blood cell counts and erythrocyte indices in the adult population of the Nordic countries *Scand J Clin Lab Invest 2004*; 64: 385-398
3. How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline – Second Edition. CLSI C28-A2

Section 5: Reagent Setup

Section Overview

Introduction

This section covers the reagent setup, changing reagents, description of reagents, and reagent consumption.

Contents

This section contains the following topics:

Topic	See Page
Reagent Description	34
Reagent Consumption	35
Reagent Setup	37
Changing Reagents	39

5.1 Reagent Description

Description

Always use reagents recommended and approved by the manufacturer. The analyzer and the reagents form a system. Each component of this system is carefully selected and designed to meet certain criteria, which can very sensitively indicate and validate system operation.

Important

- All reagents are manufactured and provided by Boule Medical AB.
- Using non-approved components of this system can cause false indications or incorrect, inaccurate measurements.
- In order to operate correctly and accurately the following reagents must be used.

Quintus 5-part Diluent	Multiple ultra-filtered, particle free buffered isotonic solution, containing stabilizers, special additives and preservatives.
Application	Quantitative and qualitative determination of RBC, WBC, PLT and HGB concentration.
Appearance	Colorless, odorless solution.
Shelf-life	24 months
Open bottle stability	90 days
Storage	Between +15 °C and +35 °C. (~59-95 °F)
Boule reagent code	1504291
Color code	Green

Quintus 5-part Lyse	Multiple ultra-filtered, particle free reagent solution, containing lysing detergents, stabilizers, leucoprotective components, special additives and preservatives.
Application	Quantitative and qualitative determination of WBC and HGB concentration.
Appearance	Colorless solution, foaming by shaking.
Shelf-life	24 months
Open bottle stability	90 days
Storage	Between +15 °C and +35 °C. (~59-95 °F)
Boule reagent code	1504292
Color code	Yellow

Quintus 5-part Stopper	Multiple ultra-filtered, particle free reagent solution, containing stabilizers, leucoprotective components, special additives and preservatives.
Application	Quantitative determination of WBC, leukocyte four-part differentiation (LYM, MONO, NEU, EOS) and hemoglobin (HGB) concentration.
Appearance	Colorless, odorless solution.
Shelf-life	24 months
Open bottle stability	90 days
Storage	Between +15 °C and +35 °C. (~59-95 °F)
Boule reagent code	1504293
Color code	Orange

Boule Hypochlorite (2%) Cleaner	Containing alkaline hypochlorite, special additives and preservatives.
Application	Capillaries, tubing and chambers, removing blood component precipitates.
Appearance	Slightly yellow liquid with chlorine odor.
Shelf-life	24 months
Open bottle stability	90 days
Storage	Between +15 °C and +30 °C (~59-86 °F)
Boule reagent code	1504113

Note The “Hypochlorite Cleaner” is not an online-reagent (not connected to the Quintus with permanent tubing.) This reagent is aspirated from a sample tube or inserted into the Quintus directly for cleaning and maintenance functions.

5.2 Reagent Consumption

Description This section describes the reagent consumption for the Quintus depending on a sample per day calculation.

Diluent Consumption Approximately 52 ml per analysis cycle.

Lyse Consumption Approximately 7 ml per analysis cycle.

Stopper Consumption Approximately 1 ml per analysis cycle.

Consumption Calculation

- The consumption can be approximately calculated depending on the number of samples per day as shown on the graphs below.
- The figures, presented in the graphs, assume one background count, one control analysis, and one exit standby are performed per day.
- The consumption relation between the Diluent and Lyse is 8:1, based on 25 samples per day.
- The consumption relation between the Diluent and Stopper is 34:1, based on 25 samples per day.

Diluent Consumption

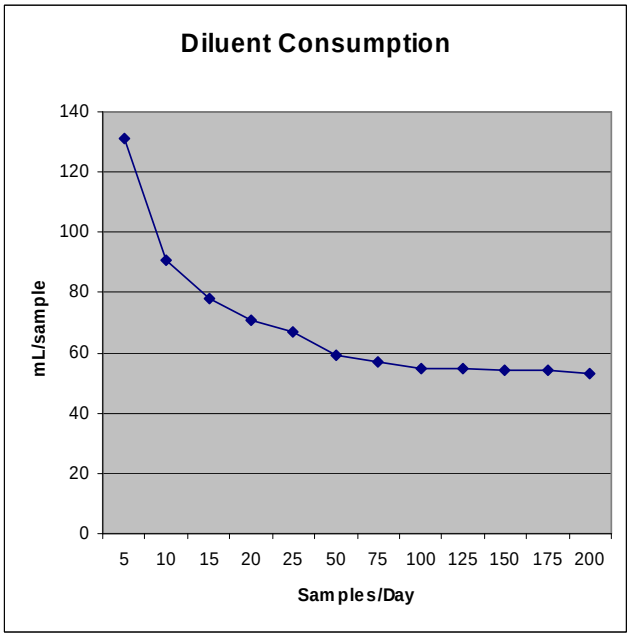


Figure 5.1

Lyse Consumption

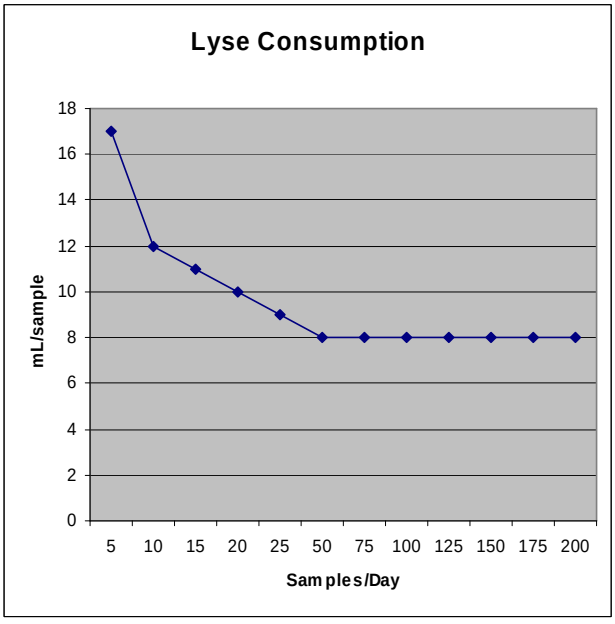


Figure 5.2

5.3 Reagent Setup

Description

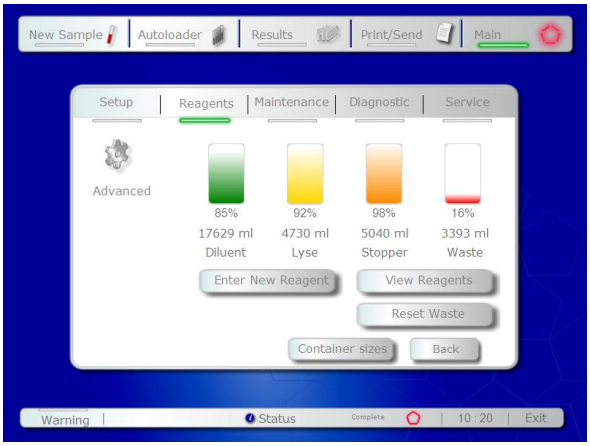
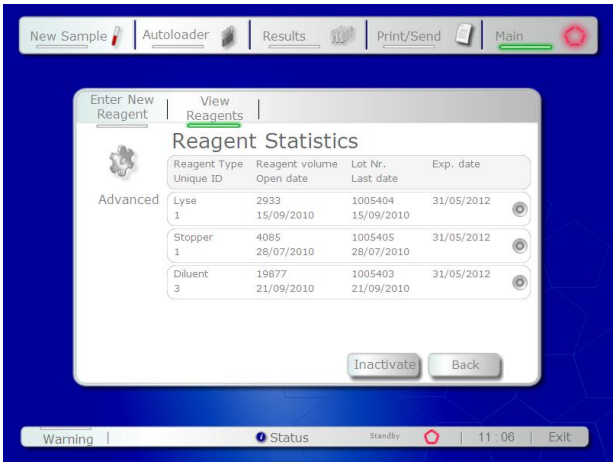
This section describes the functions of the reagent setup menu and how to access reagent statistics.

Reagent Input (Enter New Reagents)

The Quintus System is interlocked with specified Boule reagents for optimal performance. The reagent containers must be identified by the instrument before analysis of samples can begin. To identify reagents scan in or manually enter the barcodes on the reagent containers. See Section 2.4.

View Reagents

The analyzer has built-in reagent consumption calculators. The calculated level of each reagent is indicated on the screen. The height of the bar shows the level in the container. These levels are also indicated on the screen in the status area.

Step	Action
1	Start by pressing [ADVANCED] from the Main menu tab and then [REAGENTS] to enter Reagent menu.
2	In this menu you can view the amount of reagent left in each container and the calculated amount of remaining reagents in percent.
3	 Figure 5.3
Note	The reagent bars in the Reagent menu and the Status bar have both been color-coded to match the reagent inlet label on the rear of the analyzer and the reagent container label, for ease of use.
	 Figure 5.4

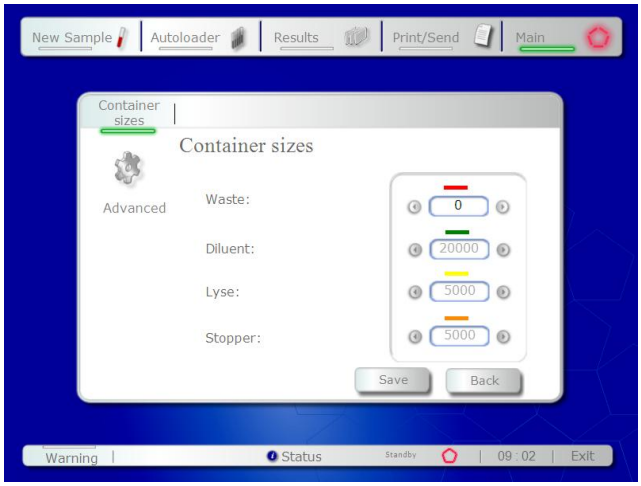
4	The third method of viewing reagent statistics is by pressing [VIEW REAGENTS] from the Reagent Setup Menu. In this screen you can view the following, for the active Lyse, Stopper, and Diluent containers: • Reagent Volume • Lot number • The expiration date of the specific reagent container. • The Open Date, when the reagent container was first used on the system. • The Last Date, when the last time that reagent container was used to run a cycle.
5	It is possible for the operator to inactivate the current reagent box by selecting the reagent and then pressing the [INACTIVATE] button and then [YES]. Once deactivated the operator must scan in or manually enter another reagent container before analysis of samples can begin. (If reagent level is adequate, an inactive reagent can be re-activated by simply scanning the barcode on the reagent container again.)

Reagent Indicators

The interlocked reagent system displays indicator and warning messages to alert the operator when reagents are running low and need to be changed.

Setting up the Waste Container

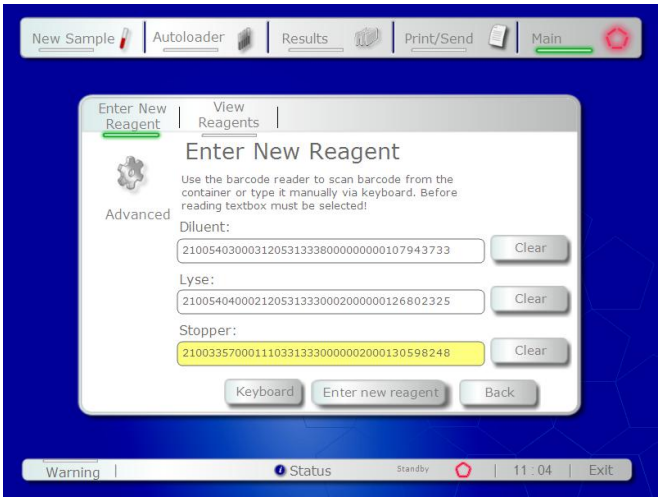
The nominal container volume of the waste can be set using the following instructions:

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [REAGENTS] and then [CONTAINER SIZES] to enter setup menu.
3	Using the scroll buttons adjust the volumes according to your container size. • If the waste tubing is plumbed directly into a drain set the value to “0”.
	 Figure 5.5
4	The waste container can be reset to “0” by selecting [RESET WASTE] button in main Reagent menu.
Note	If the waste container is almost full, according to set volume, then the Quintus warns the user to prepare for emptying the waste container.

5.4 Changing Reagents

Description

The interlocked reagent system displays indicator and warning messages to alert the operator when reagents are running low and need to be changed. When this occurs perform the following:

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [REAGENTS] and then press [ENTER NEW REAGENTS].
3	Press the text box under the reagent you will scan in (it will highlight in yellow when activated) and then scan in the barcode from the corresponding reagent container. Repeat for all applicable reagents.
	 Figure 5.6
4	Press [ENTER NEW REAGENT] to save.
5	Remove the cap and seal on the new reagent container.
6	Transfer the reagent tubing from the used container to the new reagent container.
Note	It is important when transferring the reagent tubing that it is kept clean and inserted into the correct reagent container.
7	The analyzer is now ready to resume operation or analyze samples. No priming or fill cycle is necessary when putting on a new reagent container, if indicator and warning messages are followed.

Important

A reagent alarm will display when at least one of the reagent containers is running low, empty, or expired. Once alarm is displayed it will continue to display after each sample run until the indicated container is changed.

Section 6: Sample Analysis

Section Overview

Introduction

This section covers the sample analysis routine, including how to analyze a sample in the three different modes offered in the Quintus.

Contents

This section contains the following topics:

Topic	See Page
Preparations before Analysis	40
Startup Sequence	41
Background Count	42
Sample Identification	43
Analyzing the Sample (Open Tube)	44
Analyzing the Sample (Cap Piercing)	45
Analyzing the Sample (Autoloader)	45
Results	51
Sample Memory Search Function	55

6.1 Preparations before Analysis

Sample collection

- Human venous blood samples should be collected in an EDTA K3 or EDTA K2 tube in sufficient quantity and be gently mixed immediately after sampling in order to obtain accurate results. Please follow the recommendation of the EDTA tube supplier.

Limitations

Samples drawn in an open tube or vacuum tube should be analyzed between 15 minutes and 6 hours for most accurate results.

Anticoagulant recommendation

EDTA K3 (Ethylene Diamine Tetracetic Acid, Tri-potassium) liquid and EDTA K2 (Ethylene Diamine Tetracetic Acid, Di-potassium) spray-dried solution. Recommended by ICSH and CLSI (NCCLS).

Sample tube type and size

The following 13 x 75mm sample tubes/vials can be used with the Quintus:

- Sarstedt Monovette®*
- Becton, Dickinson (BD) Vacutainer ®*
- Terumo Venosafe®*

*Registered trade mark

Important

- Please note that if using Sarstedt Monovette® sample tubes the bottom of the sample tubes are different because of the syringe.
- The sampling depth on the Quintus must be changed if a Sarstedt Monovette® sample tube is in use. See Section 4.6.

Sampling volume

The Quintus is equipped with a “piercing” needle in order to be able to aspirate samples from closed sample tubes. The aspirating hole is on the side of the needle to prevent debris and dried blood particles to pass into the sampling path. It also means that the Quintus needs at least 1 mL of sample to perform analysis accurately and with precision.

Handling of venous blood samples

- The blood should be allowed to adapt to the EDTA for 15-20 minutes after sampling.
- The sample should be thoroughly and gently mixed before analysis. It is recommended to use a mixer.
- The sample should be mixed for 10-15 minutes. A sample not correctly handled may give erroneous results.

Important

The sample should be kept at room temperature. Excessive cold or heat could cause erroneous results.

Warning

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, blood controls, calibrators and waste these products should be handled as potentially biohazardous.
- Always wear protective gloves and goggles. Follow local regulations.

6.2 Daily Startup Sequence

Startup Sequence

The following sequence walks the operator through the beginning of the day startup routine for the analyzer. There are 2 simple steps to follow which takes the user through a background and control analysis sequence. This startup sequence is optional and can be bypassed if a different startup routine is desired.

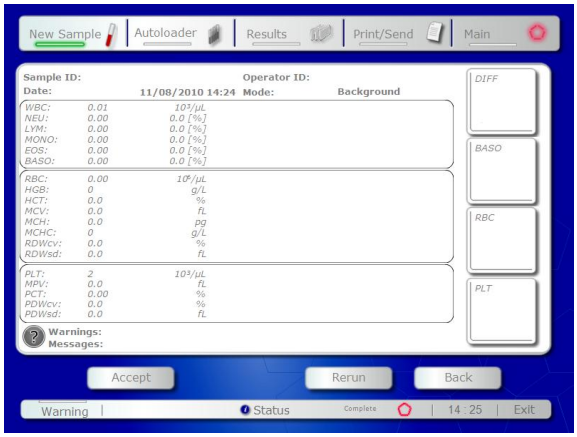
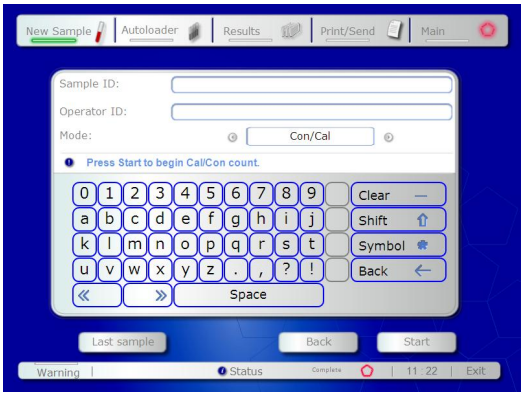
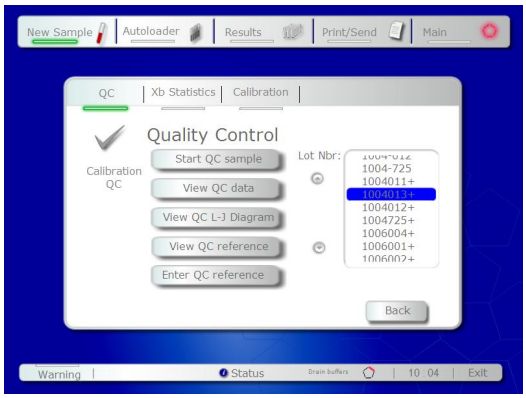
Step	Action
1	Touch display or press Standby switch on the analyzer.
2	Press [NEW SAMPLE] quick link to Startup the analyzer.
3	When complete the background count results are displayed. If the results are acceptable press [ACCEPT]. See Section 6.3.
	

Figure 6.1

Step	Action
Note	If the background count results have a H (high) indicator press [RERUN] and the background count will be analyzed again.
4	Press the [BACK] button to return to the New Sample menu.
5	Change Mode to [CON/CAL], scan in the barcode on control vial, press [START QC SAMPLE], and then [START].
	 Figure 6.2  Figure 6.3
6	When complete the control results are displayed. If control results are acceptable, then the startup sequence is complete. Press [NEW SAMPLE] to go to the main analysis screen, and follow instructions in the following sections to analyze samples.
Note	If control results have a H (high) or L (low) indicator press [START] to analyze same lot of control sample again.

6.3 Background Count

Background Check

The following sequence is performed to check that the background count is low enough to run a sample. It is recommended to run a background check at the beginning of each shift. No sample is required to analyze the background count.

Step	Action
1	From the main screen press [NEW SAMPLE].
2	Under Mode scroll to [BACKGROUND] and press [START].
3	When complete the background count results are displayed. If the results are acceptable press [ACCEPT].
Note	Background count must be accepted before a control or sample analysis can be performed.

Accepted Background values

The background count should not be higher than the figures shown below, assuming that at least 3 “backgrounds” are run after a sample.

Parameters	Values accepted
RBC	≤ 0.01 (10^{12}/ L)
WBC	≤ 0.1 (10^{9}/ L)
HGB	≤ 0.2 (g/ dL)
PLT	≤ 10 (10^{9}/ L)

6.4 Sample Identification

Description

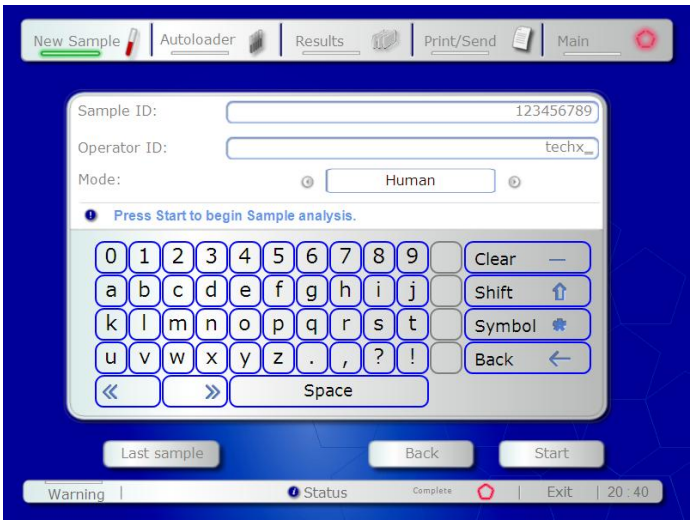
This section describes the different methods of Sample ID input (Identification).

ID Input Methods

The ID can be entered with the following methods:
- Manually (touch screen or external keyboard)
- Barcode

Character Input Limitations

- 50 Characters

Step	Action
1	From the main screen press [NEW SAMPLE] quick link to open NEW SAMPLE menu.
2	Press numerical keys to enter sample ID or scan in the ID barcode from the sample tube.
3	Use scroll buttons to choose desired mode or profile. • The Quintus has six modes pre-programmed in: Human (general), male, female, toddler, child, baby
4	Press [START] to begin sample aspiration.
Menu	 Figure 6.4
5	Aspirate sample following selected procedures in sections 6.5 – 6.7.
Note	Sample ID entry and profile selection can be performed after sample aspiration has begun, in Open Tube and Cap Piercing modes.

Operator ID

The Operator ID is an optional feature which can be entered prior to analyzing a sample or when exiting Standby Mode. To enter an Operator ID press the specified button and enter in numerical or alphabetic ID. The Operator ID will stay the same until Operator ID button is pressed again and changed, or when the analyzer goes into Shutdown Mode.

6.5 Analyzing the Sample (Open Tube)

Description

This section describes how to aspirate and analyze a sample with the “Open Tube” procedure.

Starting procedure

Refer to Section 6.1 for blood sample preparation and then follow the procedure below:

Step	Action
1	Choose [NEW SAMPLE] quick link to begin sample analysis. Analyzer must be in this menu to aspirate.
2	Enter Sample ID and select Mode. See Section 6.4 for more detail.
3	Remove cap from tube and place well mixed sample in sample rotor.
4	Start the measurement by selecting the START button on the screen or pressing the [START] button on the front panel of the Quintus.
Note	After starting the measurement the sample door will be rotated 180° (except in Background mode), the sample tube will be inside the Quintus where the aspiration of the sample will occur.

Important

- The Quintus will process the sample automatically without any human intervention. Do not hinder the sample rotor or try and remove the sample tube while it is rotating inside the system.
- If using a Sarstedt Monovette® tube, see Section 4.6.

Sample Aspiration

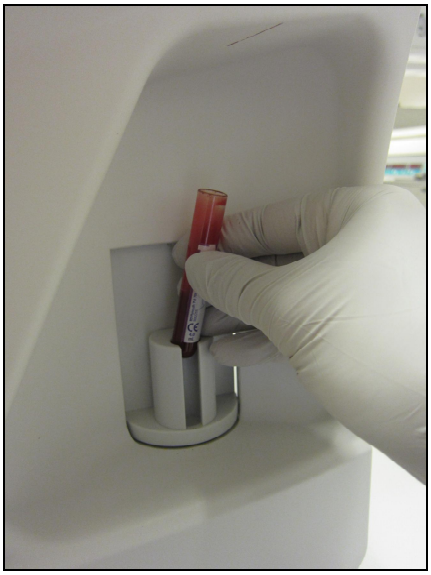
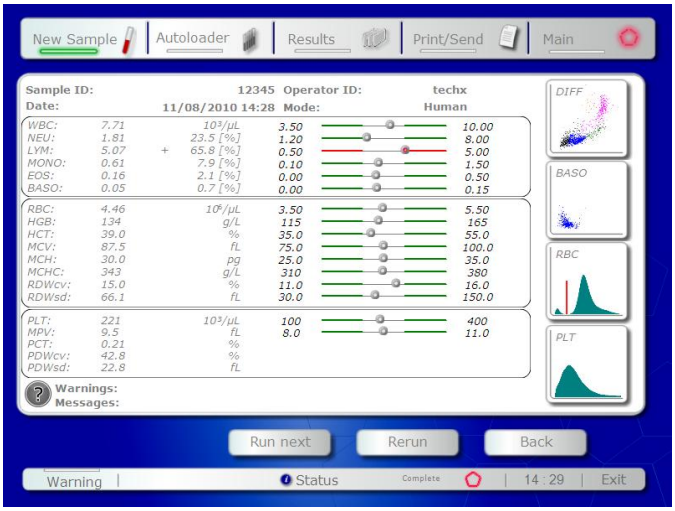


Figure 6.5

5	The results will be displayed within 60 seconds, on NEW SAMPLE and RESULTS menu. For more information of results refer to Section 6.8.
6	When START button returns to green, operator can begin analysis of next sample. (Chime will also sound when complete.)

Warning

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous.
- Always wear protective gloves and goggles. Follow local regulations.

	 Figure 6.6
Note	To re-analyze the same sample again with the same Sample ID press [RERUN] and the same sample will be analyzed again.
7	To analyze a new sample press [RUN NEXT] or [BACK].

6.6 Analyzing the Sample (Cap Piercing)

Description

This section describes how to analyze whole blood samples without removing the cap on the sample tube.

Sample tube description

See Section 6.1 for details.

Caution

The sampling needle can be damaged if incorrect type of tube is used.

Cap Piercing analysis

The Quintus uses the same sample needle for Cap Piercing. Simply follow the instruction in Section 6.5, except do not remove the cap from the sample tube.

6.7 Analyzing the Sample (Autoloader)

Description

This section describes how to analyze whole blood samples using the Autoloader (Automatic sampling device).

Sample tube description

Only closed sample tubes can be analyzed using the Autoloader.

- The QC samples and open tube analyses must be processed in Open Tube mode. See Section 6.1 and 6.5 for details.

Cap detection

The Autoloader has a built-in cap and tube type detector.

- This detector provides an extra check that no open tube vial is accidentally placed in the Autoloader racks.
- It is also able to determine the difference between Sarstedt and other vacutainer tubes.
- If the wrong type of tube or a tube without a cap is detected, the Autoloader will automatically stop, place the racks back in home position, and give a warning message to the user.

Built-in mixing device and barcode reader

The Autoloader has a built-in mixing and barcode reading device

- This mixer rotates and inverts the sample tube, similar to hand mixing
- It also is able to read the barcode on the tube automatically, no manual entry is needed.

Autoloader Modes

There are three different modes that can be used for Autoloader measurements:

- FULL SCAN mode:
  - The Autoloader will scan the whole sample tray
  - The same sample mode (Human (general), Male, Female, Baby, Toddler, Child) will be used for all the samples
  - The Sample ID is generated from the barcode (if available)
- FREE LIST mode:
  - The samples are defined on a list
  - The following parameters can be defined per sample:
    - Sample ID
    - Sample mode
  - The samples should be placed in the same order onto the sample tray as the samples defined on the list. The gaps (empty sample positions) will be skipped on the sample tray
- SELECTED SAMPLES mode:
  - For each position on the sample tray a sample can be connected
  - The defined samples will be processed only:
    - The additional samples will be skipped (not analyzed)
    - The missing samples will be marked
  - The following parameters can be defined per sample:
    - Sample ID
    - Sample mode

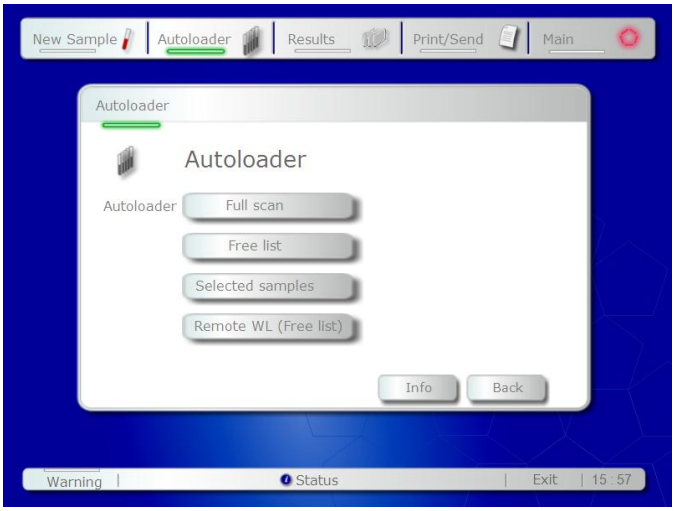


Figure 6.7

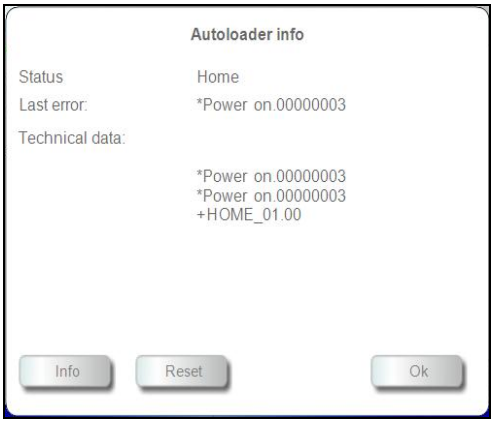
Autoloader Rack Order

The samples are scanned/ processed in the following order:

- Order of the racks: 'A' → 'J'
  - Rack 'A' is the rack at the front of the Quintus
  - Rack 'J' is the rack at the back side of the Quintus
- Order of samples inside the rack from sample '1' to sample '10'
  - Sample '1' is the sample closest to the Quintus
  - Sample '10' is the sample at the rounded edge of the cover
- A1 → A2 → … → A9 → A10 → B1 → … → B10 → C1 → …→ J10

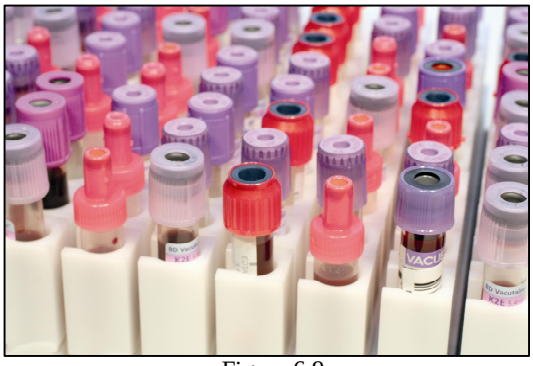
Starting procedure

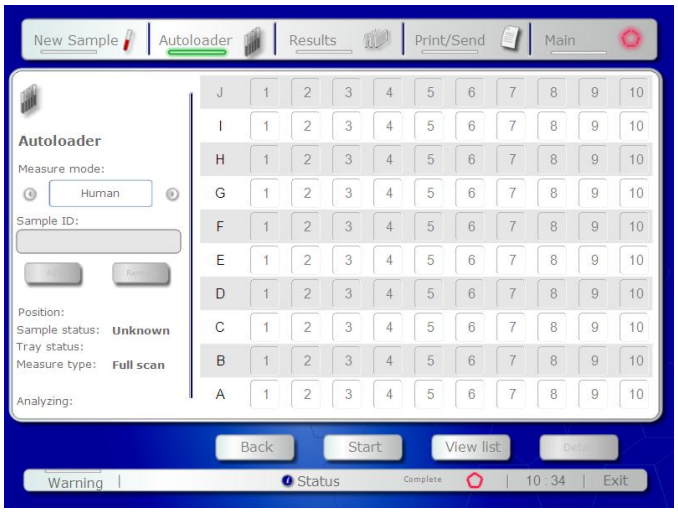
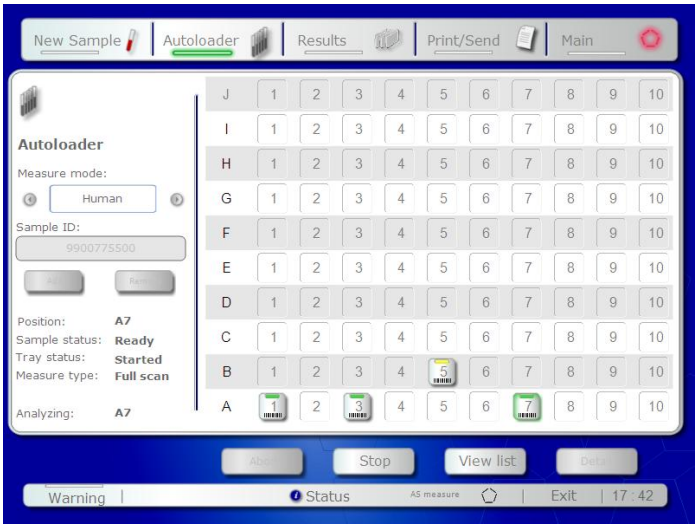
Refer to Section 6.1 for blood sample preparation and then follow the procedure below:

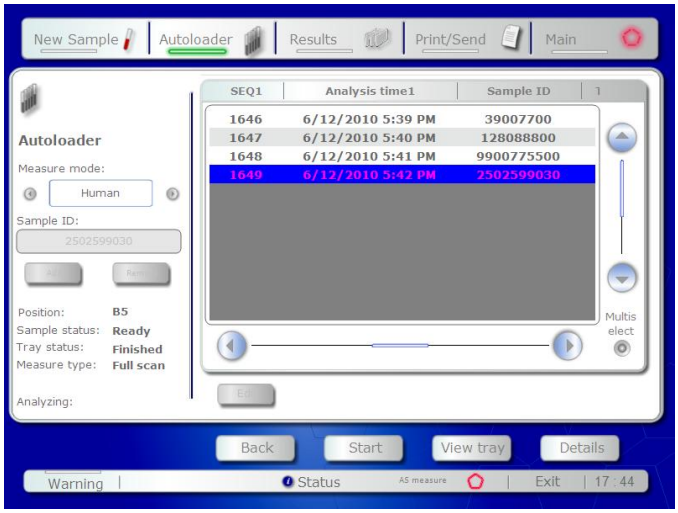
Step	Action
1	Follow Daily Startup Sequence before using the Autoloader. See Section 6.2.
2	Select [AUTOLOADER] from Main menu.
3	Select [INFO] and then [RESET]. This function will reset the Autoloader to its home position. Select [OK] to exit back to Autoloader menu
	 Figure 6.8
4	To analyze samples select which Autoloader mode works best for your laboratory. See details for each mode in the following sections.

Full Scan Mode

This mode is recommended for barcoded samples using only one measurement mode and large batches.

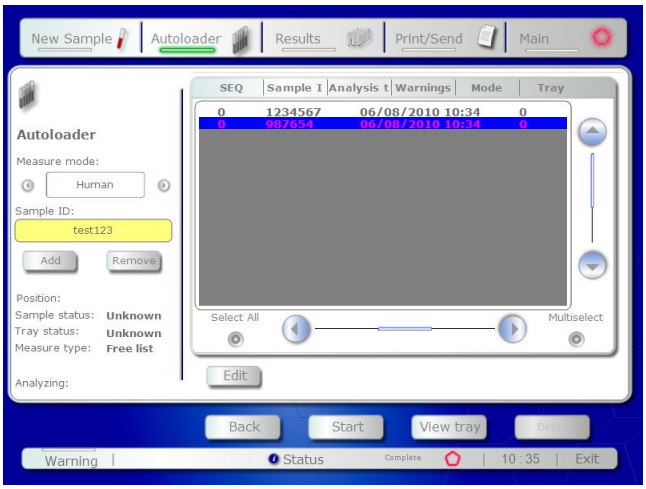
Step	Action
1	Open the cover to the Autoloader, place the samples in the racks or place loaded racks into tray.
	 Figure 6.9

Step	Action
2	Close the cover and select [FULL SCAN] button and then select Measure mode by using the scroll buttons. This mode will be used for all samples.
	 Figure 6.10
3	Press [START] button.
Note	It is recommended to place barcode labels on sample tubes. Samples without labels can be analyzed, however the Autoloader will assign a Sample ID to the sample based on it's position in the sample tray and then will prompt user to enter ID after sample is analyzed.
4	After starting the automated measurement in FULL SCAN mode: • The Autoloader will scan all the sample positions on the tray. If there is no rack then the whole row will be skipped. • If the sample can be processed (tube type identified, cap detected) then the Autoloader mixes the sample and reads the barcode. • The Quintus aspirates the sample and performs the measurement. • The progress can be followed/ monitored in [VIEW TRAY] menu. The sample currently being analyzed in highlighted around the edges in green. o By pressing on the specific sample positions, the user can see that status of that sample displayed on the left hand-side of the screen • When a sample is complete the color bar will change from yellow to green and then sample results can be viewed. (Chime will also sound after each sample is complete.)
	 Figure 6.11

Step	Action
	 Figure 6.12
5	To view sample details go to either: • [VIEW LIST] and select sample and then [DETAILS] or; • [VIEW TRAY] and select specific sample position and then [DETAILS] • [RESULTS] quick link, select specific sample and then [DETAILS]
Note	• If color bar above the rack number is red, then a sampling error occurred.
6	If the barcode below the rack number is red, then the barcode was not able to be detected and Sample ID needs to be entered once analysis is finished: • Select missing sample • Enter new sample ID in Sample ID text box and press [ADD] • After all missing sample IDs are added press [SAVE ID] to save the assigned ID.
Warning	DO NOT open the Autoloader cover after the [START] button has been pressed. All sampling will stop immediately and the Autoloader will need to be reset.
7	To add more samples to an already initiated FULL SCAN mode measurement perform the following: • Select the [STOP] button • Wait until the current sample being measured is complete • Insert the new samples: o Open the cover of the Autoloader o Place the new samples behind the last measured sample o Close the Autoloader cover • Select the [START] button The Quintus keeps track of the last analyzed sample on the sample tray of the Autoloader. After pressing [START] the Quintus instructs the Autoloader to go to the last processed position and continue the scanning from there.

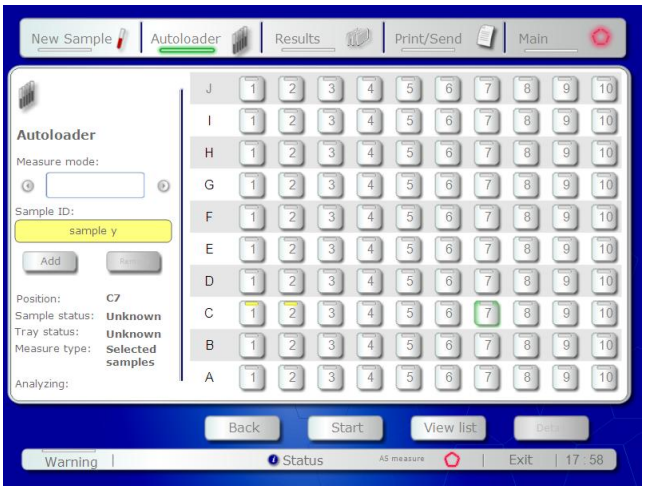
Free List Mode This mode is recommended for smaller batches, with or without barcoding, and where specific Measurement modes need to be assigned.

Step	Action
1	Select [FREE LIST] button.
2	Select Measure mode by using the scroll buttons.
3	Select Sample ID box and enter or scan in Sample ID.
4	Press [ADD] to add the sample to the list.
5	Repeat steps 2-4 until list is complete
Note	To remove a sample from the list, highlight sample, and press [REMOVE].

Step	Action
	 Figure 6.13
6	Open the cover to the Autoloader, place the samples in the racks or place loaded racks into tray, close the cover.
7	Press the [START] button.
Note	• The free list does not determine the exact position of the sample, just the position compared to the other samples. • It is not possible to add more samples to the batch in free list mode after starting the automated measurement. • If the pre-defined barcode and the detected barcode do not match, then the barcode part of the sample icon changes to red on the TRAY VIEW.
8	See Steps 4-5 in Full Scan menu for details on analysis and viewing results

Selected Samples Mode

This mode is most often used for re-running specific samples in an already measured tray. The Quintus will only look for the defined samples in this mode.

Step	Action
1	Select [SELECTED SAMPLES] button.
2	Select tray position in where this sample is located.
3	Select Measure mode by using the scroll buttons.
4	Select Sample ID box and enter or scan in Sample ID.
5	Save defined measure mode and sample ID by pressing [ADD].
	 Figure 6.14

Step	Action
6	Repeat steps 2-5 until list is complete
Note	To remove a sample from the list, highlight sample, and press [REMOVE].
7	Open the cover to the Autoloader, place the samples in the racks or place loaded racks into tray, close the cover.
8	Press the [START] button.
Note	• If a sample is defined, but no found on the tray, then the sample position will marked as problematic. • It is not possible to add more samples to the batch in free list mode after starting the automated measurement.
9	See Steps 4-5 in Full Scan menu for details on analysis and viewing results

Emergency Sample Analysis

Emergency (STAT) samples can be analyzed after the Autoloader has been started.

Step	Action
1	Select the [STOP] button and wait until the current sample being measured is complete.
2	Place the urgent sample into the sample rotor, the same as you would for an normal Open or Closed tube measurement (See Section 6.5)
3	As soon as the current Autoloader measurement is finished, select the [NEW SAMPLE] quick link, enter in Sample ID, and press [START].
4	When urgent sample analysis is complete, return to the Autoloader menu by selecting [AUTOLOADER] quick link.
5	Restart the measurement selecting the [START] button again.
Note	The Quintus will continue the automated measurement where from it was interrupted

6.8 Results

Description

This section describes the information that can be obtained from the sample analysis results.

Detailed result screen

The result screen of the Quintus is divided into four areas:

1. Sample information
2. Parameters
3. Histograms and scatter diagrams
4. Information and Warning messages

To view the detailed results for a sample, select the sample under the RESULTS menu and then press the [DETAILS] button. The [NEW SAMPLE] quick link can be used to quickly see the last sample analyzed.

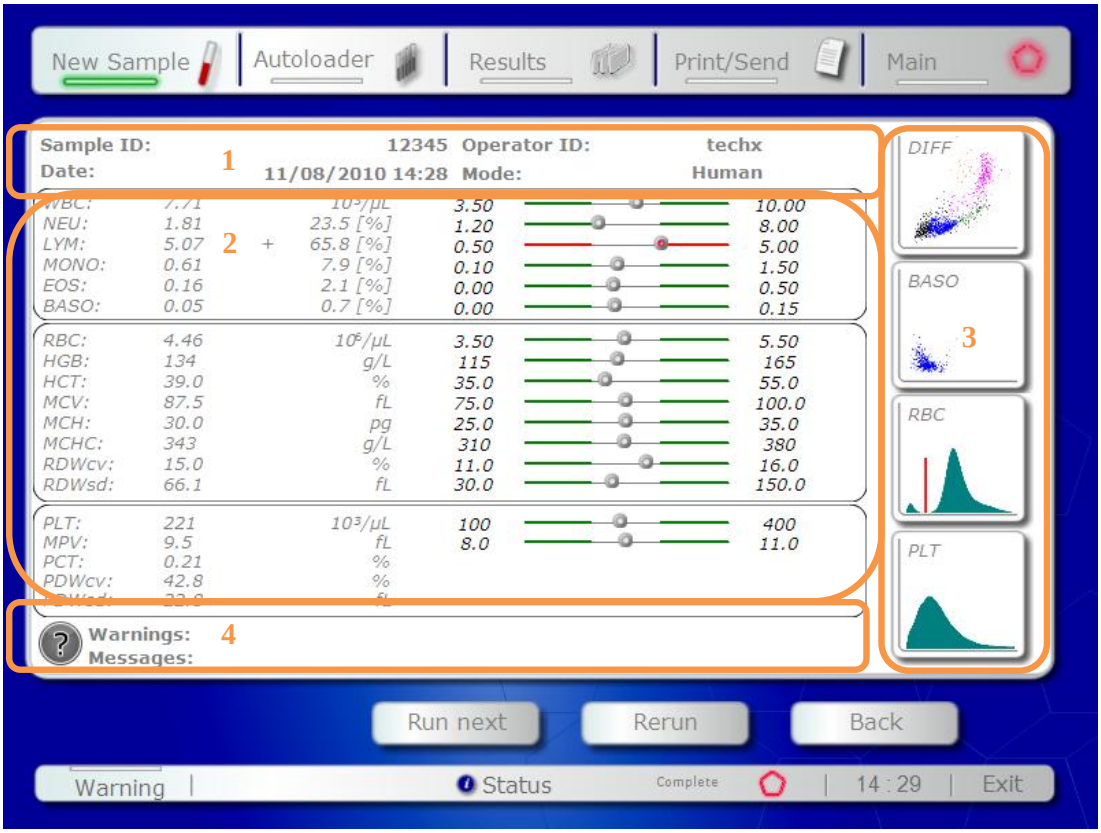


Figure 6.15

Step	Action
1	Sample Information - This section of the detailed results screen displays the following information: • Sample ID • Date and Time of when the sample was analyzed • Operator ID • Measurement Mode
2	Parameters - This section of the screen displays: • Result values from current analysis • Units • Normal (Profile) ranges along with colored range bar o Red bar - Results Out-of-Range o Green bar- Results within range • Out-of-range or Error warning - See Section 10 for further details
3	Histograms and scatter diagrams - This section of the screen displays: • 4-part differential scatter diagram • Basophil scatter diagram • RBC and PLT histogram • Magnified PLT historgram
Note	The histograms and the scatter diagrams are active areas – you can click on them and get magnified images of the actual drawings.
4	Information and Warning messages - See Section 10 for further details • Press on the question mark, to see more detailed information about the message

Scatter diagrams and Histograms

Scattergrams and histograms can be enlarged by pressing on smaller image.

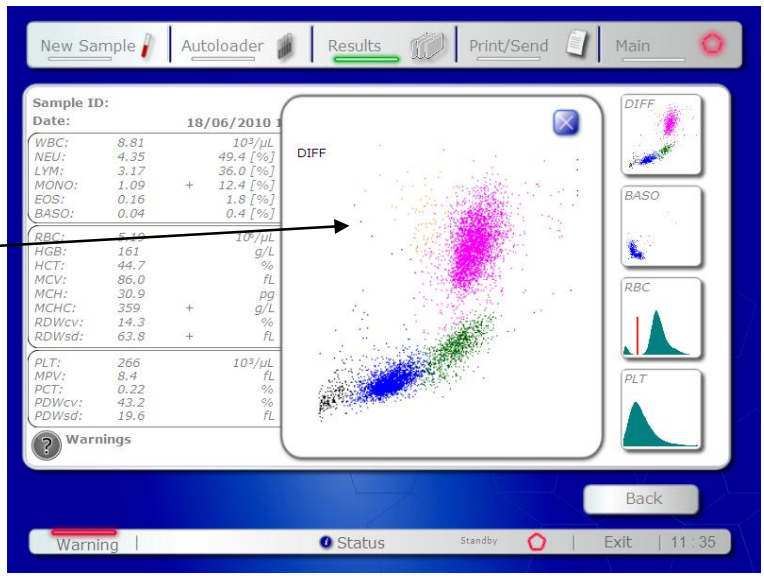


Figure 6.16

Scatter diagrams

Quintus displays the results of the optical measurements in a scatter diagram representation.

- Scatter diagrams represent data in a two-dimensional plane.
- There are two scatter diagrams in the patient report: the 4-DIFF and the BASO.

4-part Differential scatter diagrams

These scatter diagrams displays cells identified after the first selective lysing process. Due to the measurement technology, cells are classified based on their optically detected properties: low and high angle scattered light intensity. The optical detector can measure intensity of the light scattered of diffracted from or through each cell. One portion of this light is proportional to size of the cell, the other value is proportional to the complexity of the internal structures in the cell.

Due to the fact that each cell in a population acts alike, they can be easily grouped based on the values acquired during the optical analysis. Therefore these similar cells can be grouped, and identified. Different colors help identifying various populations of blood cells.

Population (4-diff diagram)	**Color on scatter diagram**
Artifact	BLACK
Lymphocytes	BLUE
Monocytes	GREEN
Neutrophil granulocytes	MAGENTA
Eosinophil granulocytes	ORANGE

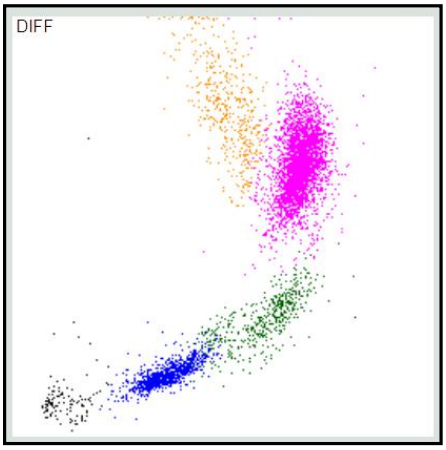


Figure 6.17

Population (Basophil diagram)	Color on scatter diagram
WBC without Basophil	BLUE
Basophil granulocytes	MAGENTA

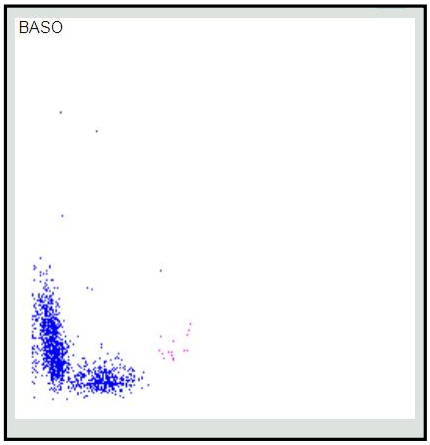


Figure 6.18

Histograms

Impedance based measurements are represented on histograms. These diagrams show the number of cells against cell size.

- There are two histograms: RBC and PLT.
- Discriminators (thresholds) are displayed with red color.
- The PLT histogram is the magnified section of the left-hand side of the RBC curve.

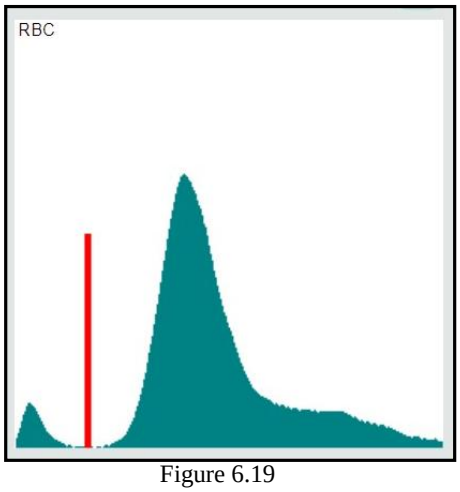


Figure 6.19

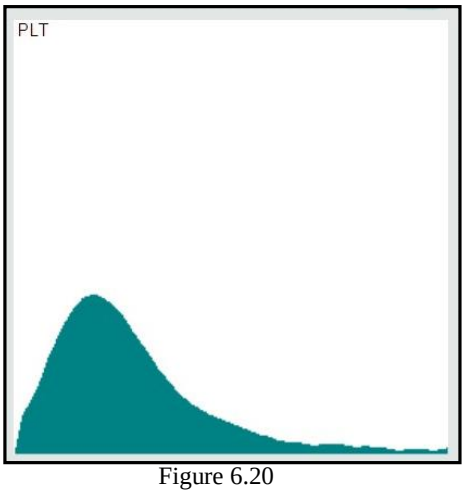
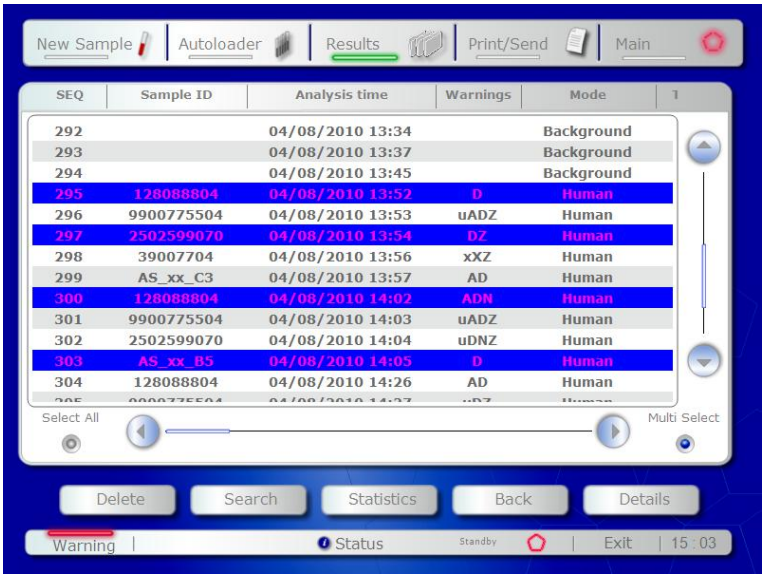


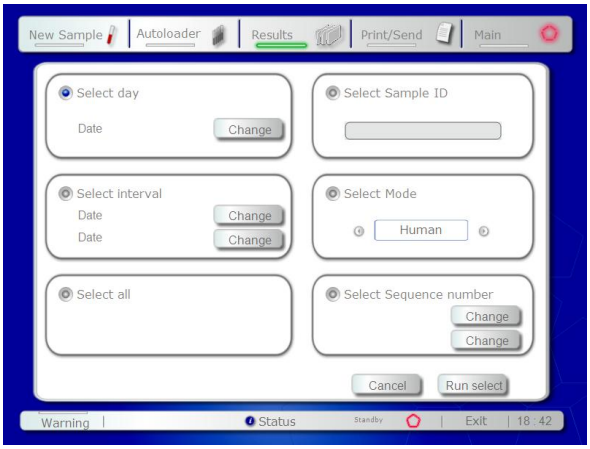
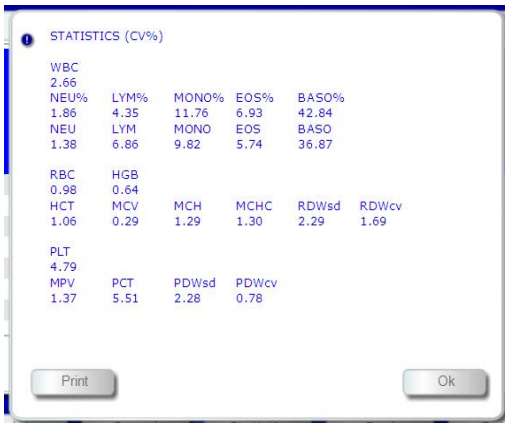
Figure 6.20

6.9 Searching and Sending Results

Searching for Results

The following procedures explain how to search for previous sample analyses and statistics, and print, send, and delete samples.

Step	Action
1	Choose [RESULTS] from Main menu. • Each row represents a sample measurement. • Each column represent a parameter
2	To search through the parameters use the LEFT and RIGHT scroll buttons or the scroll bar.
3	To search for a specific samples use the scroll buttons, the scroll bar, or the [SEARCH] function. • The UP and DOWN scroll buttons will allow user to search line by line • The scroll bar can be used to scroll through many pages of samples quickly • To select more than one sample at a time, then please turn on the multi-select mode by activating the MULTI SELECT checkbox. • To select all samples activate the SELECT ALL checkbox.
	 Figure 6.21
4	To search for a group of samples press [SEARCH]. In this menu samples can be selected by: • Select day: select measurement which were made on a given day • Select interval: select measurement which were made between two given dates • Select all: selects all sample analyzed in the database • Select Sample ID: selects a specific Sample ID number • Select Mode: selects all samples in a specific mode • Select Sequence number: selects measurements within a defined sequence number range
5	Select checkbox to activate search criteria.
6	Enter or change search criteria.
7	Select the [RUN SELECT] button to start the selection process. Only those samples selected will be seen in the results screen.

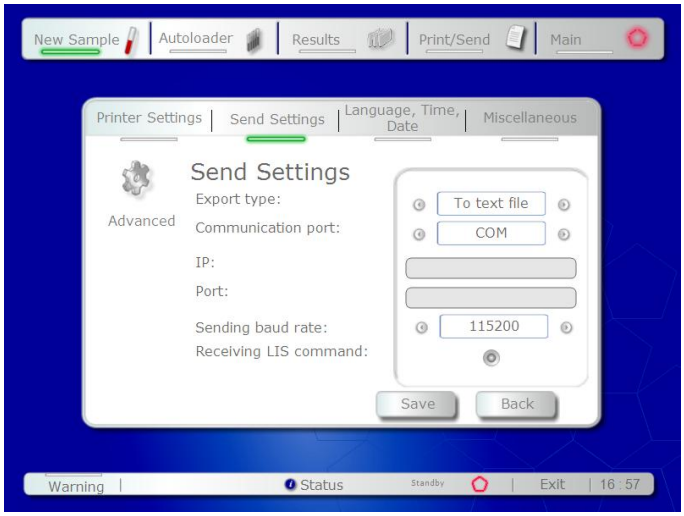
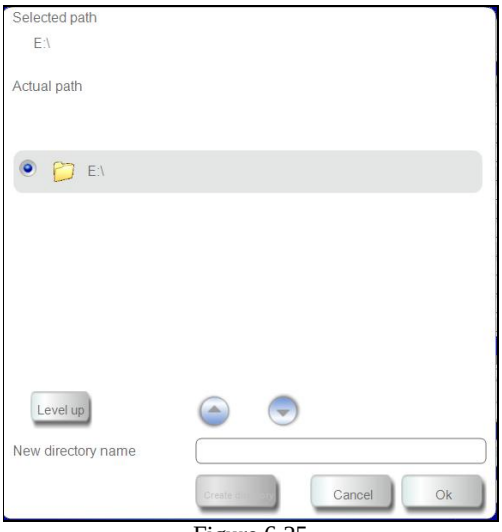
Step	Action
	 Figure 6.21
Note	• To return to previous selection criteria either press [SEARCH], then [SELECT ALL], and then [RUN SELECT] or analyze a new sample. • Press [CANCEL] to exit Search function.
3	To view sample statistics (CV%), select sample or group of samples to view, and press [STATISTICS].
	 Figure 6.22
4	To print selected sample or sample statistics press the [PRINT/SEND] quick link • The results can be printed individually or in a table format
5	To delete selected sample or group of samples press [DELETE]. The instrument will display a prompt to enter an authorization code to verify deletions, press [**555**] and then [OK].
	 Figure 6.23

Sending results

This section contains instructions on how to export data to:

- Text files
- LIS

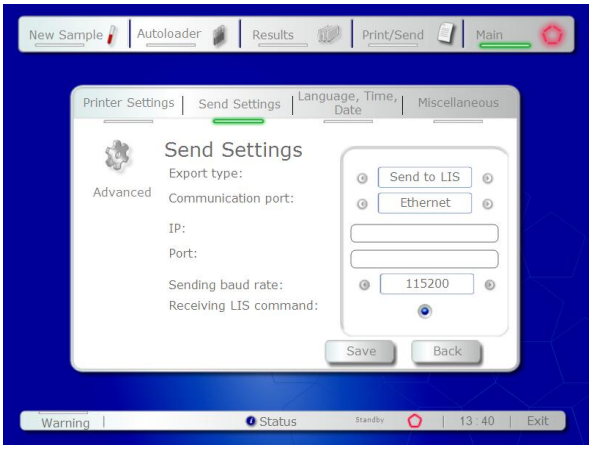
Export Text files

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [SEND SETTINGS] to enter the Send setup.
3	Change the Export Type to [TO TEXT FILE] and press [SAVE]. See Section 4.4.
	 Figure 6.24
4	Connect the USB storage device (e.g. memory stick) to the Quintus.
5	Select [RESULTS] quick link and choose samples using the search methods described in section above “Searching for Results”.
6	To send selected sample or sample statistics press the [PRINT/SEND] quick link.
7	Select the desired target folder and press [OK] to send.
	 Figure 6.25
Note	The file format is described in the Appendix of this manual.

Export to LIS

There are two main possibilities to upload the measurement data to a host system for further processing:

- Use the “3.1 protocol” over a serial port
- Use the LIS / HL7 (v2.5) over the IP stack.

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [SEND SETTINGS] to enter the Send setup.
3	Change the Export Type to [SEND TO LIS] and press [SAVE]. See Section 4.4.
	 Figure 6.26
4	For the 3.1 Protocol based connection: • Install a “3.1 protocol” compatible software on your hosts computer • Build up a serial link (null modem, modem eliminator) between the Quintus and the host system. On the Quintus use the COM1 port on the back side of the Quintus. • Configure the serial connection: o Set Communication port to [COM 1] o Set Sending Baud rate to either [9600] or [115200]. (If connection cable is longer than 5m (15 inches) choose 9600. o On the host computer start up the desired software and: ▪ Select the same speed ▪ Select the serial port where the cable is connected • Send the selected records from Quintus to the host computer o Select [RESULTS] quick link and choose samples using the search methods described in section above “Searching for Results”. o To send selected sample or sample statistics press the [PRINT/SEND] quick link.
Note	To use an application other than 3.1 Protocol, contact your sales or service representative.
5	For the LIS/HL7 based connection: • Configure the IP stack on the Quintus: o Contact the local IT administrator and collect information about the local network and the desired IP settings of the Quintus: ▪ DHCP ▪ Fixed IP (IP, Net-mask and Default router (if necessary)) o Ask sales or service representative to configure the local IP stack on the Quintus. • Configure the LIS properties in SEND menu: o Activate Receiving LIS Command by selecting the checkbox o Enter the IP address of the host computer o Enter the listener port of the host computer • Send the selected records from Quintus to the host computer using same procedure as that for the 3.1 Protocol.

Section 7: Quality Control (QC) and Blood Control Memory

Section Overview

Introduction

The Quintus is equipped with an advanced QC program which allows the user to scan in QC Assay Values and control material, along with a QC memory capable of displaying and printing Xb and Levey Jennings plots.

Contents

This section contains the following topics:

Topic	See Page
Quality Control (QC)	59
Levey-Jennings Plots	62
Initialization and Use of Xb Function	63

7.1 Quality Control (QC)

Introduction

This section describes the procedures to be performed for running control samples.

QC Menu and Assay Value Input

Follow the instruction below to access the QC menu and to enter Control/Calibrator Assay Values from the Assay sheet.

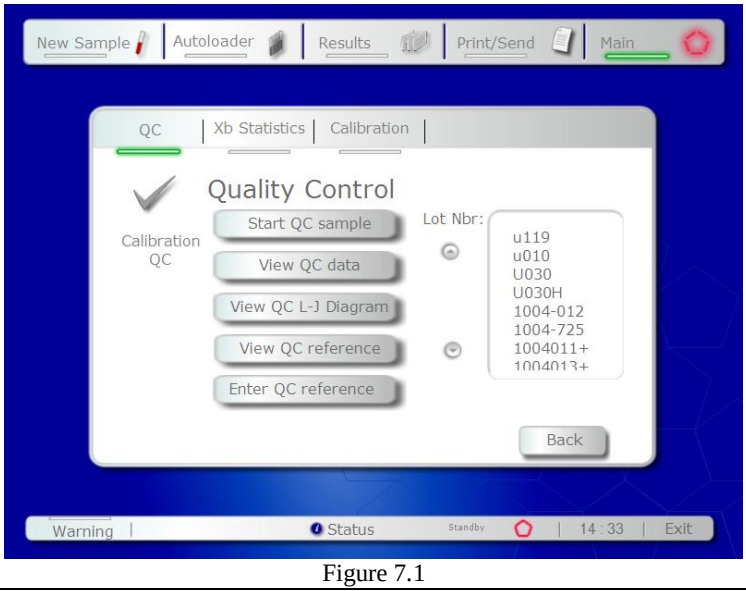
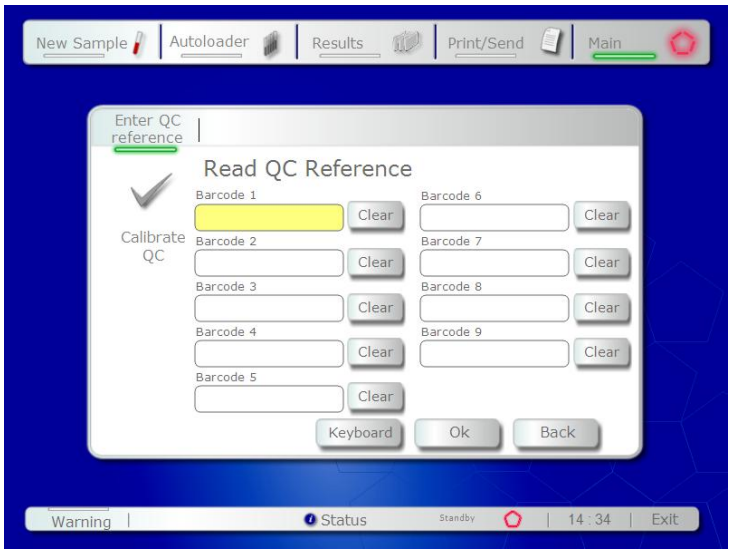
Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [CALIBRATION/QC] and then [QC] to enter QC setup.
	

Figure 7.1

Step	Action
3	Press [ENTER QC REFERENCE] and highlight the text box under Barcode 1.
	 Figure 7.2
4	Refer to the Assay sheet for instructions on how to enter Assay Values. (These pages are delivered with authorized Boule controls).
5	Select [OK] to save values.
6	Select [BACK] and new lot number can now be seen on the main QC menu
Note	Assay values only need to be scanned in once per lot, they are stored in the Quintus memory once entered.

Control Analysis It is recommended that the performance of the Quintus system is checked daily with certified blood controls authorized by Boule.

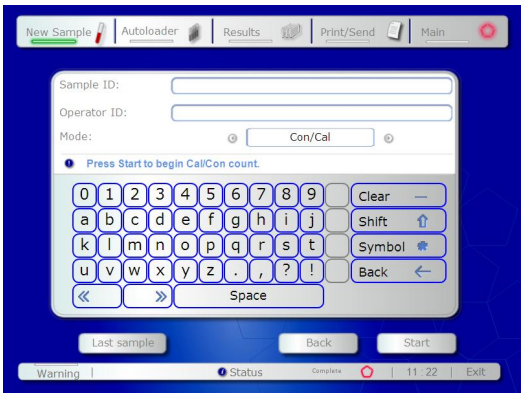
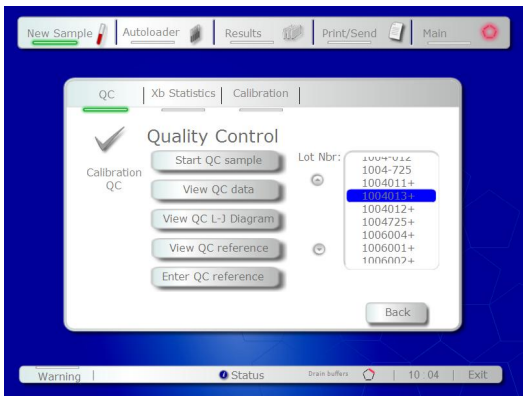
Important

- Handle and prepare controls in accordance to control package insert.
- Never use an open vial longer than recommended by the manufacturer or subject any vial to excessive heat or agitation.

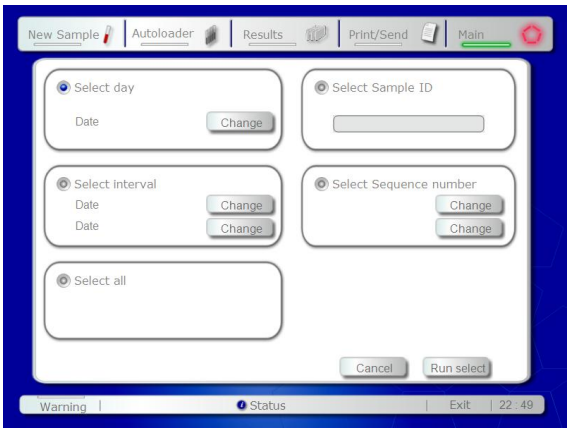
Warning

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous.
- Always wear protective gloves and goggles. Follow local regulations.

Step	Action
1	Choose [NEW SAMPLE] quick link to begin control analysis.
2	Change Mode to [CON/CAL].
3	Using installed external barcode reader, scan the Control ID from the blood control vial label.
4	Select [START QC SAMPLE], insert the well mixed blood control vial into sample rotor, and then press [START].
Note	The Control lot can also be selected from the main QC menu in the right-hand column if barcode is damaged.

Step	Action
	 Figure 7.3  Figure 7.4
6	When complete the control results are displayed. The Quintus identifies the QC lot and match the results with the previously defined control assay values.
Note	If control sample results have a H (high) or L (low) indicator press [START] to analyze same lot of control sample again.
7	The Result screens, search, print, and send functions for QC samples are similar to patient samples.

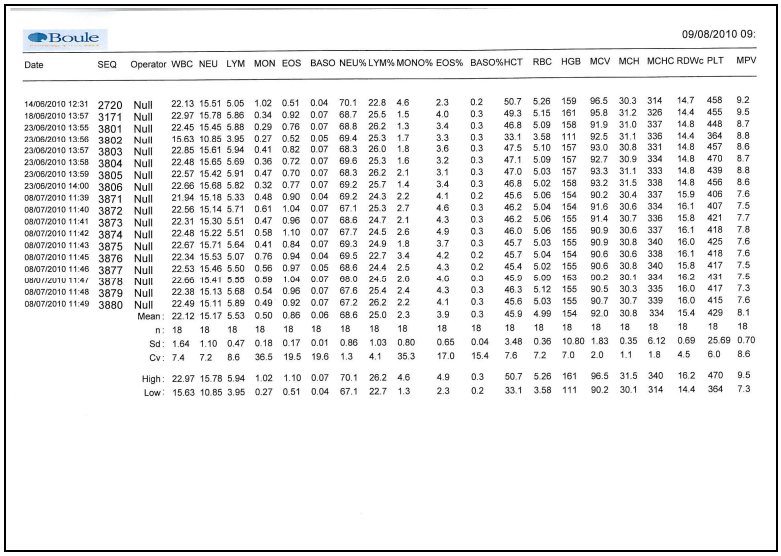
Search Function Each blood control type can be found by control lot number, date or sequence number.

Step	Action
1	The quickest way to for searching for a particular control or calibrator lot number is to select the desired lot number from the main QC menu in the right-hand column and then press [VIEW QC DATA].
2	For a more advanced search select [VIEW QC DATA] and then [SEARCH]. Select one of the following search criteria: Day, Date interval, All, Lot ID, and Sequence numbers.
3	Select checkbox to activate search criteria and enter or change the search criteria
4	Select the [RUN SELECT] button to start the selection process. Only those samples selected will be seen in the results screen.
	 Figure 7.5
Note	• To return to previous selection criteria either press [SEARCH], then [SELECT ALL], and then [RUN SELECT] or analyze a new sample. • Press [CANCEL] to exit Search function.
5	To print selected sample press the [PRINT/SEND] quick link • The results can be printed individually or in a table format

Monthly QC Report

A monthly QC report can be printed out in a table format per lot of control. To print a Monthly QC summary report :

Step	Action
1	Under main QC menu select the desired Control lot number.
2	Select [VIEW QC DATA] and then [SEARCH].
3	Activate SELECT INTERVAL and change the dates to the corresponding month.
4	Press [RUN SELECT] to save the entry.
5	Activate the SELECT ALL checkbox.
6	Select [PRINT/SEND] quick link, choose [TABLE FORMAT] and then [OK].



Boule 09/08/2010 09:

Date	SEQ	Operator	WBC	NEU	LYM	MON	EOS	BASO	NEU%	LYM%	MONO%	EOS%	BASO%	HCT	RBC	HGB	MCV	MCH	MCHC	RDWc	PLT	MPV
14/08/2010 12:31	2720	Null	22.13	15.51	5.05	1.02	0.51	0.04	70.1	22.8	4.6	2.3	0.2	50.7	5.26	159	96.5	30.3	314	14.7	458	9.2
18/06/2010 13:57	3171	Null	22.97	15.78	5.86	0.34	0.92	0.07	68.7	25.5	1.5	4.0	0.3	49.3	5.15	161	95.8	31.2	326	14.4	455	9.5
23/06/2010 13:55	3801	Null	22.45	15.45	5.88	0.29	0.76	0.07	68.8	26.2	1.3	3.4	0.3	46.8	5.09	158	91.9	31.0	337	14.8	448	8.7
23/06/2010 13:56	3802	Null	15.63	10.85	3.95	0.27	0.52	0.05	69.4	25.3	1.7	3.3	0.3	33.1	3.58	111	92.5	31.1	336	14.4	364	8.8
23/06/2010 13:57	3803	Null	22.85	15.61	5.94	0.41	0.82	0.07	68.3	26.0	1.8	3.6	0.3	47.5	5.10	157	93.0	30.8	331	14.8	457	8.6
23/06/2010 13:58	3804	Null	22.48	15.65	5.69	0.36	0.72	0.07	69.6	25.3	1.6	3.2	0.3	47.1	5.09	157	92.7	30.9	334	14.8	470	8.7
23/06/2010 13:59	3805	Null	22.57	15.42	5.91	0.47	0.70	0.07	68.3	26.2	2.1	3.1	0.3	47.0	5.03	157	93.3	31.1	333	14.8	439	8.8
23/06/2010 14:00	3806	Null	22.66	15.68	5.82	0.32	0.77	0.07	69.2	25.7	1.4	3.4	0.3	46.8	5.02	158	93.2	31.5	338	14.8	456	8.6
08/07/2010 11:39	3871	Null	21.94	15.18	5.33	0.48	0.90	0.04	69.2	24.3	2.2	4.1	0.2	45.6	5.06	154	90.2	30.4	337	15.9	406	7.6
08/07/2010 11:40	3872	Null	22.56	15.14	5.71	0.61	1.04	0.07	67.1	25.3	2.7	4.6	0.3	46.2	5.04	154	91.6	30.6	334	16.1	407	7.5
08/07/2010 11:41	3873	Null	22.31	15.30	5.51	0.47	0.96	0.07	68.6	24.7	2.1	4.3	0.3	46.2	5.06	155	91.4	30.7	336	15.8	421	7.7
08/07/2010 11:42	3874	Null	22.48	15.22	5.51	0.58	1.10	0.07	67.7	24.5	2.6	4.9	0.3	46.0	5.06	155	90.9	30.6	337	16.1	418	7.8
08/07/2010 11:43	3875	Null	22.67	15.71	5.64	0.41	0.84	0.07	69.3	24.9	1.8	3.7	0.3	45.7	5.03	155	90.9	30.8	340	16.0	425	7.6
08/07/2010 11:45	3876	Null	22.34	15.53	5.07	0.76	0.94	0.04	69.5	22.7	3.4	4.2	0.2	45.7	5.04	154	90.6	30.6	338	16.1	418	7.6
08/07/2010 11:46	3877	Null	22.53	15.46	5.50	0.56	0.97	0.05	68.6	24.4	2.5	4.3	0.2	45.4	5.02	155	90.6	30.8	340	15.8	417	7.5
08/07/2010 11:47	3878	Null	22.66	15.41	5.55	0.59	1.04	0.07	68.0	24.5	2.6	4.0	0.3	45.9	5.09	153	90.2	30.1	334	16.2	431	7.5
08/07/2010 11:48	3879	Null	22.38	15.13	5.68	0.54	0.96	0.07	67.6	25.4	2.4	4.3	0.3	46.3	5.12	155	90.5	30.3	335	16.0	417	7.3
08/07/2010 11:49	3880	Null	22.49	15.11	5.89	0.49	0.92	0.07	67.2	26.2	2.2	4.1	0.3	45.6	5.03	155	90.7	30.7	339	16.0	415	7.6
		Mean:	22.12	15.17	5.53	0.50	0.86	0.06	68.6	25.0	2.3	3.9	0.3	45.9	4.99	154	92.0	30.8	334	15.4	429	8.1
		n:	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18
		Sd:	1.64	1.10	0.47	0.18	0.17	0.01	0.86	1.03	0.80	0.65	0.04	3.48	0.36	10.80	1.83	0.35	6.12	0.69	25.69	0.70
		Cv:	7.4	7.2	8.6	36.5	19.5	19.6	1.3	4.1	35.3	17.0	15.4	7.6	7.2	7.0	2.0	1.1	1.8	4.5	6.0	8.6
		High:	22.97	15.78	5.94	1.02	1.10	0.07	70.1	26.2	4.6	4.9	0.3	50.7	5.26	161	96.5	31.5	340	16.2	470	9.5
		Low:	15.63	10.85	3.95	0.27	0.51	0.04	67.1	22.7	1.3	2.3	0.2	33.1	3.58	111	90.2	30.1	314	14.4	364	7.3

Figure 7.6

7.2 Levey-Jennings Plots

Procedure instruction

This section describes selecting, viewing, and printing Levey-Jennings Plots.

L-J Plots

Levey-Jennings (L-J) plots are used to monitor the long term stability of the instrument using Boule blood controls.

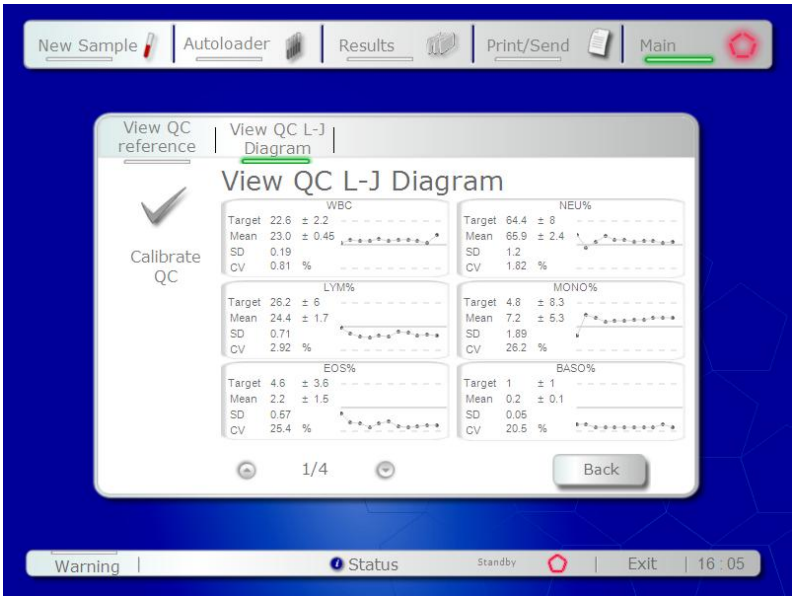
Blood controls

To be able to use L-J plots, the Control/Calibrator Assay Values for the blood controls **must** be scanned with the installed barcode reader or manually entered in. Follow direction on Assay Sheet to scan in assay values.

Displaying and printing L-J Plots

To display and print the L-J plots, follow the instructions below:

Step	Action
1	Enter the QC menu and select the desired lot number from the main QC menu in the right-hand column.
2	Select [VIEW QC L-J DIAGRAMS] to display the Levey - Jennings plots.
3	Use the scroll buttons to view the different parameters, there are 4 pages.

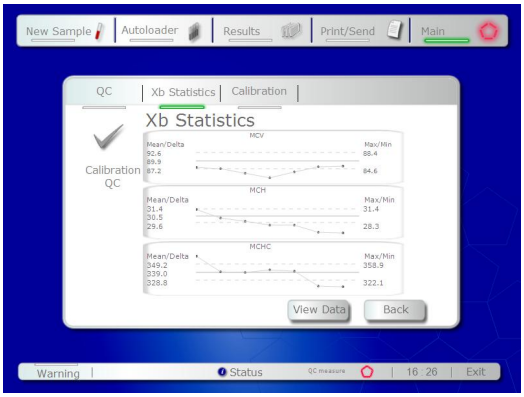
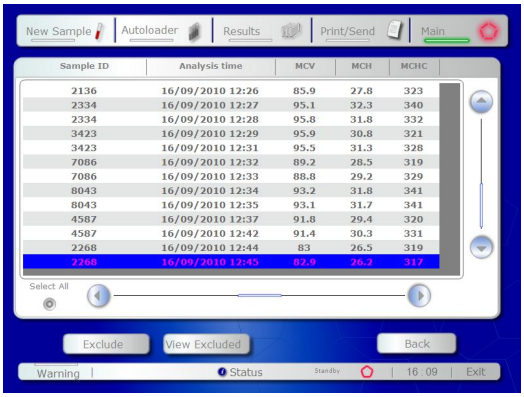
Step	Action
	 Figure 7.7
Note	• The mean, standard deviation (SD) and coefficients of variation (CV) are calculated based on the QC analyses. • The dotted lines delineate acceptable ranges on Levey-Jennings plots. • Image 7.6, above, is constructed from several samples and will not be shown as above until a sufficient amount of samples have been analyzed.
4	Print all diagrams by choosing [PRINT/SEND].

Note In case a control shows a system information indicator, the parameter values of such control will not be included in the L-J plots.

7.3 Initialization and Use of Xb Function

Description The Xb function in the Quintus follows strictly the Bull algorithm for the parameters MCV, MCH and MCHC. These parameters should not drift as a function of time within a large patient population. The recommended range setting is ± 3% from the expected mean value of these parameters.

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [CALIBRATION/QC] and then [Xb STATISTICS] to view plots.
3	Print all diagrams by choosing [PRINT/SEND].
4	Choose [VIEW DATA] to view data selection. By default all sample data is selected.
5	To exclude samples from the Xb data plots highlight sample to be removed and select [EXCLUDE].
6	To view excluded items select [VIEW EXCLUDED]. In this menu the user can also include the sample back into the plots by selecting [UNDO EXCLUDE].

Step	Action
	The image below is constructed from several samples and will not be shown as below until a sufficient amount of samples have been analyzed.
	 Figure 7.8  Figure 7.9
7	To change ranges on Xb Diagrams see Section 4.8

Reference Bull BS, Hay KL. The blood count, its quality control and related methods: X-bar calibration and control of the multichannel hematology analysers. In: Clangoring I. editor. Laboratory Hematology: An account of Laboratory Techniques. Edinburgh.

Section 8: Calibration

Section Overview

Introduction

This section describes the step-by-step procedure for calibration of the Quintus. The instrument has been calibrated by Boule prior to shipment. Good laboratory practice, however, requires regular checks and calibration of the measured parameters. It is recommended to calibrate the instrument when needed.

Contents

This section contains the following topics:

Topic	See Page
Preparations before calibration	65
Calibration	66

8.1 Preparations before calibration

Before Calibration

- It is recommended that the performance of the Quintus system is checked daily with certified blood controls authorized by Boule.
- Analyze control blood once in the open tube mode and compare results with the assigned values prior to calibration.
- Verify that nothing is erratic with the control blood, the reagents, or the instrument before calibrating instrument.
- Verify that instrument maintenance/cleaning is current. (See Sections 9.1 – 9.3)
- Prior to calibration print Calibration Log. Select [CALIBRATION/QC] from Main menu, then [CALIBRATION], then [VIEW CALIBRATIONS], select latest calibration, and then [PRINT/SEND].

Important

- The user should be thoroughly familiar with the analyzer system and the calibration procedure before performing calibration.
- Refer to the Calibrator Product Insert for complete instructions for handling and use of blood calibration materials.
- Never use an open vial longer than recommended by the manufacturer or subject any vial to excessive heat or agitation.

Warning

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous.
- Always wear protective gloves and goggles. Follow local regulations.

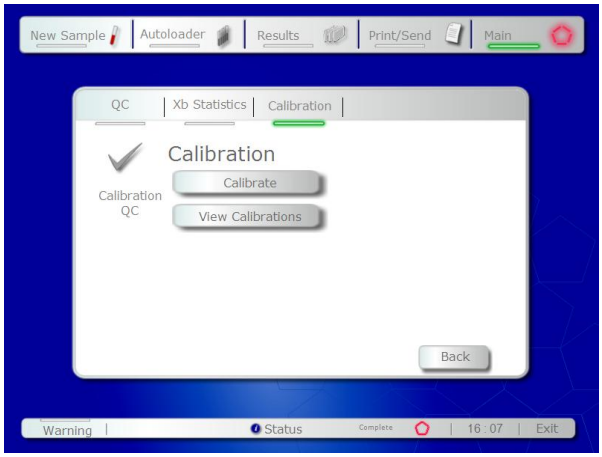
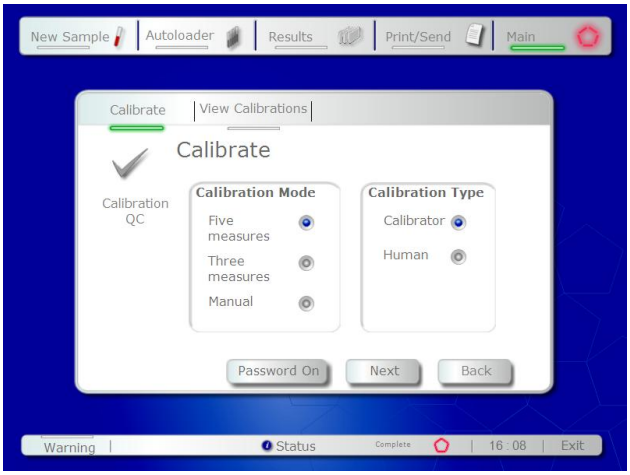
8.2 Calibration

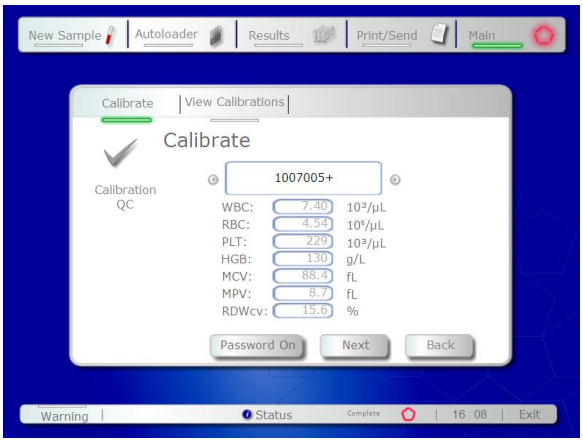
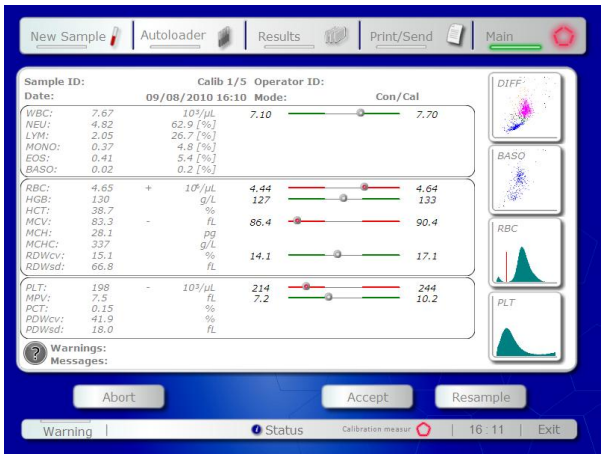
Input Calibrator Assay Values

Follow the instruction in Section 7.1 Quality Control to access the QC menu and to enter Control/Calibrator Assay Values from the Assay sheet.

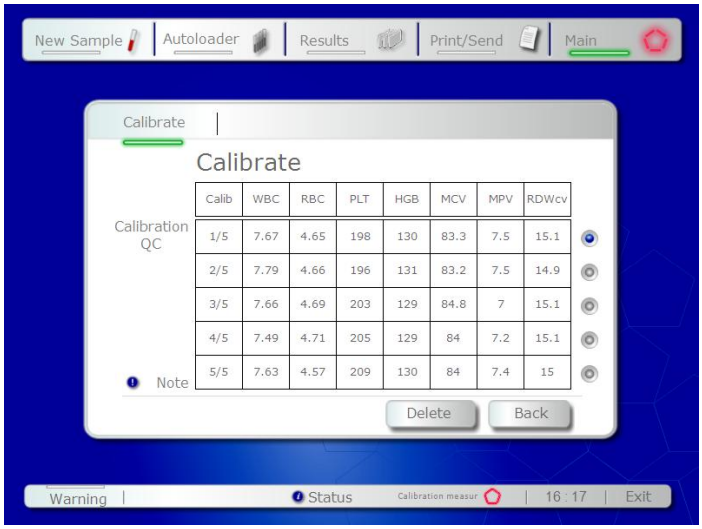
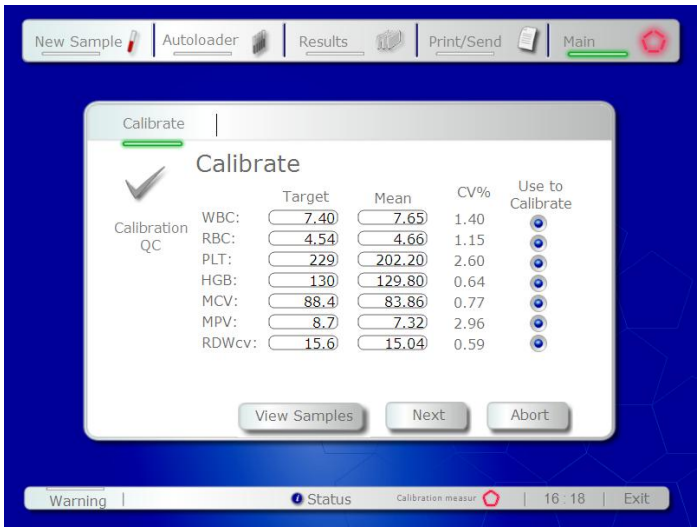
Whole Blood Calibration

The following instructions calibrate Open Tube, Cap Piercing, and Autoloader modes. Follow the instructions below to calibrate:

Step	Action
1	Follow directions on Assay Sheet to scan in calibrator assay values.
2	Select [CALIBRATION/QC] from Main menu and then [CALIBRATION].
3	Authorized operators can update or change calibration factors only by entering the Authorization Code [**1234**].
	 Figure 8.1
4	Select Calibration Mode: Five measures, Three measures, or Manual.
5	Select Calibration Type: Calibrator or Human
Note	• It is recommended that five calibration analyses be performed in consecutive order through the open tube mode. (e.g. calibration process will be aborted if in the middle of calibration a patient sample analysis is performed) • The Quintus uses a different method to process QC samples than processing human samples, it is recommended to use Calibrator.
	 Figure 8.2
6	Select [NEXT] to continue.

Step	Action
7	Choose which Calibrator to use for calibration by using scroll buttons and then [NEXT] to continue. • The range of the target values for the Calibrator are linked to the pre-entered Assay sheet values. • If [HUMAN] was selected it will skip this screen and go the next one.
	 Figure 8.3
8	Select [START] to begin calibration.
9	After each measurement you have to accept the results by selecting [ACCEPT] or re-run that measurement by selecting [RESAMPLE]. (For a 5 sample calibration you need 5 accepted measurements.)
	 Figure 8.4
Note	Only press [ABORT] to exit calibration. This function will cancel all runs and take you back to the Main menu.
10	After 5 measurements have been accepted the Quintus will display the following: • Target value • Mean – If outside of the calibrator normal range, this box will be highlighted red. • CV% - If outside of acceptable CV% value, these values will be highlighted yellow.

Parameter	CV%
RBC	≤ 2.2
MCV	≤ 1.8
PLT	≤ 5.8
HGB	≤ 1.8
WBC	≤ 4.2
MPV	≤ 4.0
RDW%	≤ 4.0

Step	Action
11	If the Mean or CV% are outside of the limits operator will be unable to perform calibration. To view the sample analyses select [VIEW SAMPLES].
	 Figure 8.5
12	To delete samples select which sample you would like to delete and select [DELETE] button. • When a sample is deleted it will ask you if you would like to run another sample or abort the calibration. o [RERUN] will rerun the sample o [ABORT] will cancel the entire calibration o [BACK] will return you to the previous menu
13	When Mean and CV% is acceptable, select which parameters to calibrate by selecting the Use to Calibrate checkbox, and then select [NEXT].
	 Figure 8.6
14	• If the required number of measurements are completed and accepted, then the Quintus calculates and displays the new factors. • The currently valid factors and the CV of the measurements are also displayed. • You can review the new factors and make them effective by selecting [ACCEPT] or discard the changes by selecting [DISCARD].
Note	It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. See Section 7.1 to perform QC.

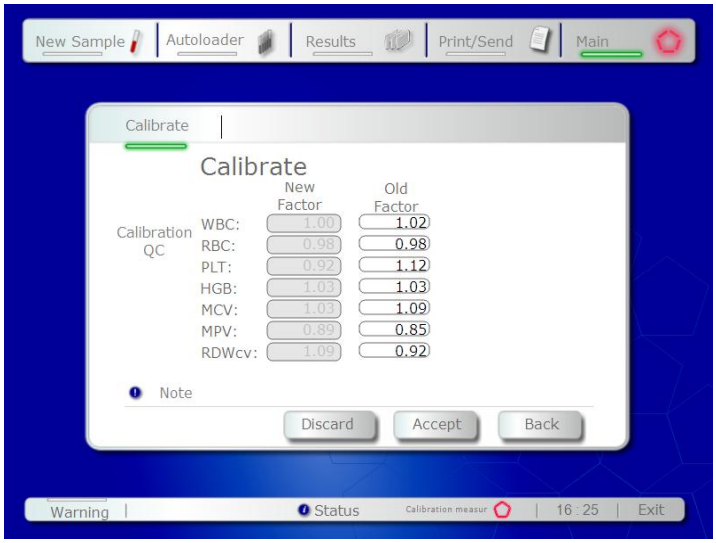
Step	Action
	

Figure 8.7

Manual Calibration

When you selected MANUAL for calibration mode, blood type and target value entry are disabled. The [NEXT] button takes you to the manual factor entry screen.

- Values displayed in parentheses are actual calibration factors. To modify a value, tap the box of the value.
- Calibration factors for each parameter can range from 0.80 to 1.20.
- Values outside this range result in an error message.
- To save factors, select [ACCEPT].

Section 9: Cleaning, Maintenance & Transport

Section Overview

Introduction

This section contains information that is crucial for maintaining, transporting and storing the Quintus.

Contents

This section contains the following topics.

Topic	See Page
Daily Cleaning	70
Shear Valve Cleaning	71
Cleaning, As Needed	74
Instrument Maintenance	76
Re-location of instrument (within the laboratory)	76
Short Term Transport (<12h)	76
Re-packaging and Long Term Transport	77
Permanent Shut-Down and Storage	78
Disposal Information	78

9.1 Daily Cleaning

Description

The majority of the instruments cleaning procedures are automated to keep the user maintenance to an absolute minimum.

Warning

Always use gloves when in contact with potentially biohazardous materials or parts of the instrument that might be contaminated with blood.

Daily Cleaning Procedure

The Daily Cleaning takes about five minutes and should be performed at the end of the day, the instructions are as follows:

Step	Action
1	Select [EXIT] from Main menu and then [SHUTDOWN] or [OVERNIGHT CLEAN]. Instructions will be given to place Cleaner solution into sample rotor.
Note	It is recommended to use Overnight Clean for this cleaning function. See Section 4.9 for setup.
2	Remove cap from vial with Boule Hypochlorite Cleaner, place in the sample rotor and then press [OK].
Note	Even though the Quintus can pierce the cap of a sampling tube, the rubber caps are not designed for multiple punctures. Therefore, it is recommended to remove the cap of the vial with the cleaning solution, to prevent the rubber from hardening and eliminate any small rubber particles which could clog the aspiration needle.
3	Cleaning process takes a few minutes, once complete remove Cleaner vial, recap and store until next use.

9.2 Shear Valve Cleaning

Description

Any salt build-up on the inner surface of the shear-valve may cause malfunction during operation. **To avoid this problem, it is recommended to clean the shear valve after every 1500 samples or every month.**

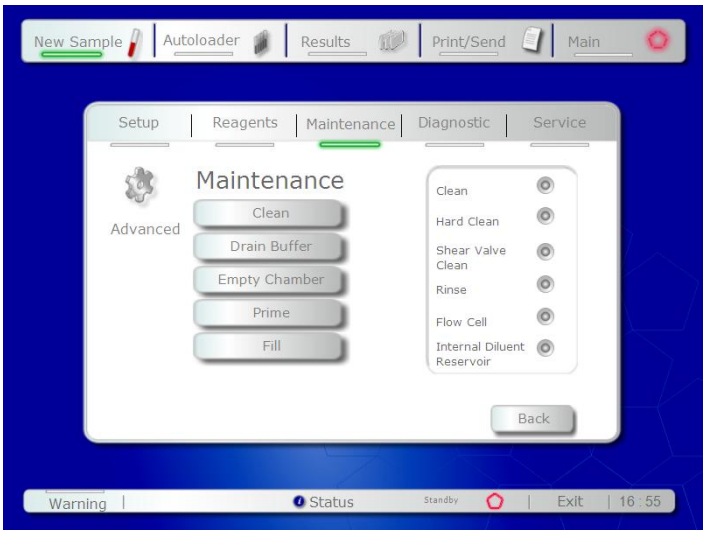
Warning

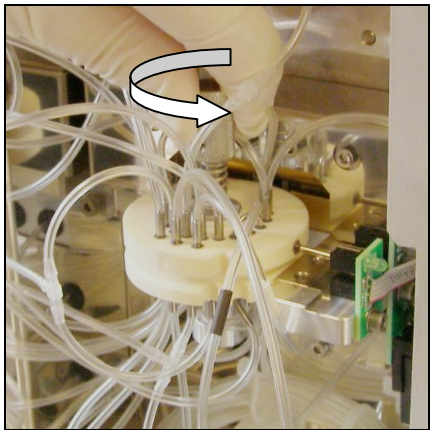
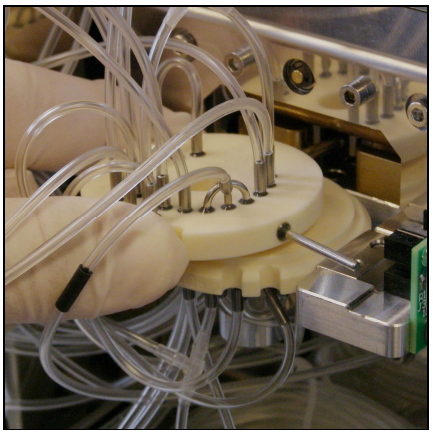
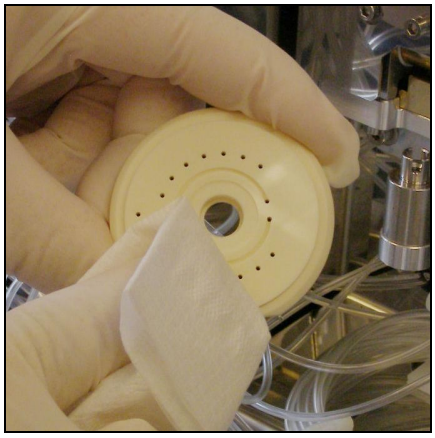
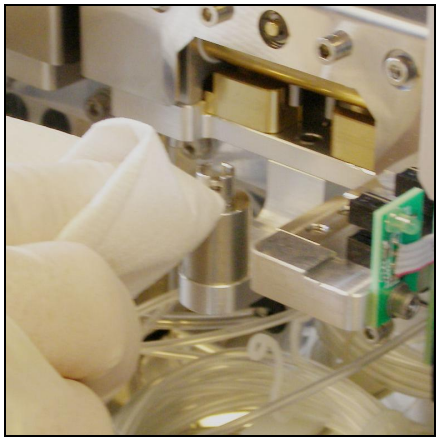
Always use gloves when in contact with potentially biohazardous materials or parts of the instrument that might be contaminated with blood.

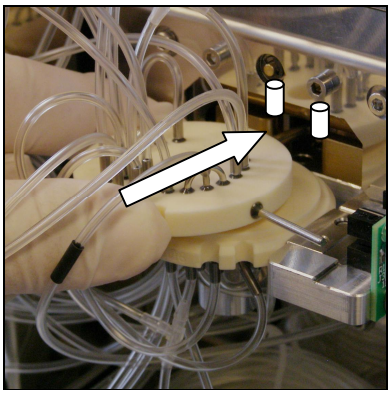
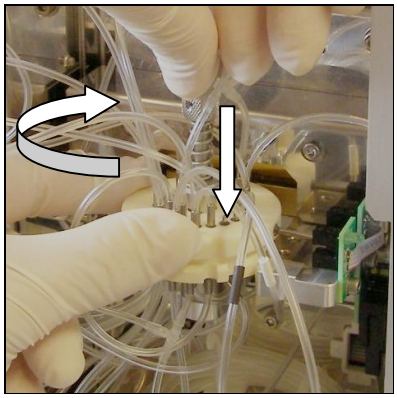
Cleaning procedure

This procedure takes approximately 5-10 minutes, and the following materials are needed:

- Distilled water
- Gloves
- Gauze pads or other soft, lint-free cloth

Step	Action
1	Select [ADVANCED] from Main menu and then [MAINTENANCE].
	 Figure 9.1
2	Select [SHEAR VALVE CLEAN] checkbox. The Quintus asks for confirmation to start the procedure. Confirm by pressing [OK] and the procedure empties the shear valve and the connecting tubes.
3	As the preparations completed the Quintus displays the instructions on how to proceed. • **Do not press the [OK] until the shear valve is assembled again.**
4	Open the front cover, and secure it with the latch. • Make sure that nothing is placed on the top, or in front of the analyzer. Grab the lower sides of the front panel, gently pushing the sides. Pull the lower part towards you, and lift it up. • Upon opening, a lever becomes visible. Make sure to tilt the front panel upwards so that you can push the lever into the secure position.

Step	Action
	 Figure 9.2
5	Unscrew the Axis screw, by turning it counter-clockwise, and remove by gently but firmly pulling it upward from shear valve. Clean Axis screw with water and wipe it dry.
	 Figure 9.3  Figure 9.4
6	Remove the upper disk from the shear valve by gently pulling it forward and slightly upward. The two disks will have some surface tension from the remaining liquid in the shear valve. Avoid hitting optical sensors located on the right side of the shear valve holding plate.
	 Figure 9.5  Figure 9.6
7	Wipe any possible salt crystals off the upper and lower discs with a wet, lint-free cloth. Clean the housing/ mounting of the shear valve paying special attention to cleaning the aligning surfaces.

Step	Action
Note	Do not use any sharp/ metal / hard objects to clean the shear valve, as they can scratch the surface of the shear valve.
	 Figure 9.7  Figure 9.8
8	After cleaning the shear valve, the housing and surrounding area, put the disks together.
9	Put the axis screw through the upper and lower disk. Gently press and rotate the screw until the lip of the screw is flush with the top of the upper disk and tighten clockwise until the axis screw is hand-tight.
10	Gently lower the front panel. When it reaches its lowest position, gently push on the front side to click the lock levers into place.
11	Select [OK] and the Quintus will check the movement and end positions of the shear valve.
12	Go to [NEW SAMPLE] and run a few backgrounds to clear any remaining salt crystals. If the results are acceptable press [ACCEPT] and analyzer is ready to analyze a sample.

9.3 Cleaning, As Needed

Description

This section describes the cleaning procedure to be used to secure the correct function of the instrument over time. The cleaning time internal is dependent on the instrument usage and handling.

- Less than 50 samples/day = every three months
- More than 50 samples/day = every month

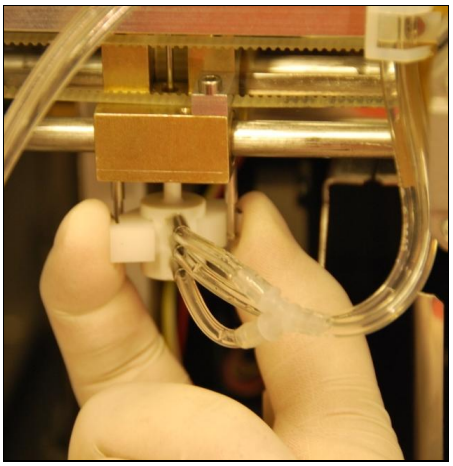
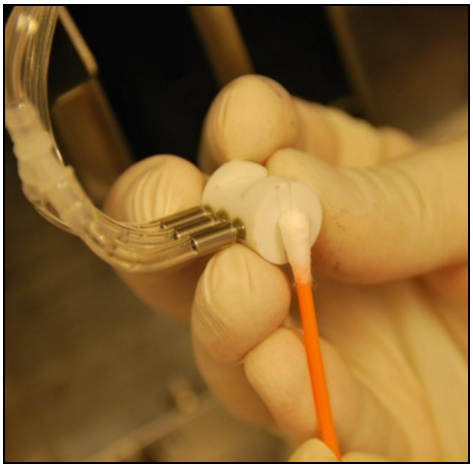
Touch Screen Cleaning

When necessary, gently clean the display with a soft cloth, slightly moistened with water and a mild soap. Dry carefully.

Wash Head Cleaning

The washing head cleans the outer surface of the aspirating tip with diluent. Any salt build-up on the lower surface may cause malfunction during operation. The wash head must be removed from the needle assembly for correct cleaning. This procedure takes approximately 5-10 minutes, and the following materials are needed:

- Distilled water
- Gloves
- Gauze pads, soft, lint-free cloth or cotton swab

Step	Action
1	Open the front cover, and secure it with the latch.
2	The right-hand side panel of the analyzer must be removed to access the wash head. Loosen the 2+2 screws on the front and rear of the side panel. The panel can be gently pulled up and off the analyzer.
3	The wash head should be “twisted off” from the needle, and pulled off downwards. Use a soft cloth or cotton swab dampened with water to clean the bottom of the wash head.
	The sampling needle is sharp, and can cause injury. Be careful when removing and replacing the wash head.
	 Figure 9.14  Figure 9.15
4	Replace the wash head back by pushing the wash head onto the needle and lock it back into place by twisting it onto the holding rods.
5	Replace the side cover and close the front panel.
6	Go to [NEW SAMPLE] and run a few backgrounds to clear any remaining salt crystals. If the results are acceptable press [ACCEPT] and analyzer is ready to analyze a sample.

High Background Cleaning

If the background measurement result is too high during a background analysis, despite regular cleaning, use the built-in cleaning process to clean the system. This process can take up to 30 minutes.

Step	Action
1	Select [ADVANCED] from Main menu and then [MAINTENANCE].
2	Follow instruction for Daily Cleaning procedure in Section 9.1.
3	Go to [NEW SAMPLE] and run a few backgrounds to verify background is acceptable. If acceptable choose [ACCEPT] and analyzer is ready to analyze a sample.
4	If the background is still too high, return to [MAINTENANCE] and select [INTERNAL DILUENT RESERVOIR].
5	Instructions will be given to place a full vial of Cleaner solution into sample rotor.
6	Remove cap from vial with Boule Hypochlorite Cleaner, place in the sample rotor and then press [OK].
7	Once complete, return to Step 3 and re-analyze background. 5-6 backgrounds may need to be analyzed to complete clear out hypochlorite from the system.

9.4 Instrument Maintenance

Description

This section describes the maintenance that is required to maintain and increase the life of the instrument. Refer to local distributor for warranty requirements.

Maintenance

The maintenance should be performed at the following intervals by local distributor or authorized service technician:

- 6 months or 20,000 samples

9.5 Re-location of instrument (within the laboratory)

Description

This section describes the procedure performed to move the instrument over **very short** distances. (From table to table).

Before the re-location

Place the instrument in Shutdown mode using [EXIT] button and then turn the main power switch to OFF. (This is the small switch near the power cord.)

Step	Action
1	**Do not** detach the reagent or waste tubing. Remove the tubing with caps from the reagent containers and place the tubing on top of the instrument when moving.
2	Remove the waste tubes from waste container or drain, but do not detach tubes from analyzer.
3	Disconnect all electrical connections.

Re-location

See Section 2.1 for lifting and placing the analyzer in the new location.

After re-location

Step	Action
1	Place the waste tubes in waste container or drain.
2	Reconnect the electrical connections.
3	Insert the reagent tubing with caps back into the reagent containers.

9.6 Short Term Transport (<12h)

Description

This section describes the procedure performed before transporting the instrument over short distances. This procedure **only** describes the preparations performed before transporting the instrument for less than 12 hours.

Short Term Transport

- Follow direction in Section 9.5 except disconnect the reagent and waste tubing from the analyzer.
- Package all components carefully for transport.
- The instrument should be transported in temperature conditions between 5 to 30 ºC (41 to 86 ºF)
- Humidity should be less than 80%.

9.7 Re-packaging and Long Term Transport (>12h)

Description

This section describes the procedure when transporting or shutting down the instrument for a longer period of time (>12 hours). Required tools:

- Prepare for shipment tube set
- Distilled water (or RO–water)

Important

It is very important to follow the below instructions for preparing the analyzer for long term transport or re-packaging, to avoid erroneous results upon re-installation.

Long term Shut-Down

Step	Action
1	Press [EXIT] button from MENU tab and then [SHIPMENT].
2	The analyzer will guide you through the Prepare for shipment process step by step. This process takes about 30 minutes. (Each step will take about 10 minutes.) • The first instructions will be to disconnect the reagent tubing from the back, but not the waste tubing. Then the system will drain the liquid system. • The second instructions will be to connect distilled water to the reagent inlets. Use the special reagent tubing with three connectors for this process. • The system will perform priming and full rinsing of the tubing system. Do not turn the analyzer off during this process. • The third instructions will be to disconnect the reagents from the back, except the waste. The system will drain all liquids from the analyzer.
3	When shipment procedure is complete, the system will ask the operator to switch off the analyzer. Press [OK] and wait for the analyzer to exit and perform the shutdown procedure.
4	Switch off power and then unplug analyzer.
5	Disconnect the main supply cable and other connections such as reagent and waste tubing, barcode reader, printer, etc.
6	Tight up the shear valve and put back the safety card, see section 2.3.
7	Pack the instrument using the original shipping container.
8	Mark the container with DELICATE INSTRUMENT, FRAGILE and THIS SIDE UP.
9	Follow Guidelines for transport below.

Guidelines for transport

The instrument in its export package should fulfill the following transport/storage conditions:

- Does not exceed –40°C (–40°F) for ≥24 hours.
- Does not exceed a Dry heat of 70°C (+158°F) for ≥24 hours.
- Dramatic change of temperature between -40°C (–40°F) and 30°C (+86°F).
- Does not exceed a Damp heat steady state of 90% RH and 40°C (+104°F) during 48 hours.
- Does not exceed a Damp heat cyclic of 90-100% RH and +25°/+40°C (+77°/+104°F) 12+12 hours.

9.8 Permanent Shut-Down and Storage

Permanent Shut-Down and Storing

See Section 9.7 Long Term Transportation.

9.9 Disposal Information

Description

Customers are advised to be knowledgeable of applicable local, state and federal requirements, and the content of effluent streams, before disposing of waste in public sewer systems or recycling decontaminated equipment.

Disposal Materials

- Used reagents
- Reagents mixed with potentially biohazardous material
- Instrument and instrument components
- Controls and calibration material

Manufacturer Guidelines for waste products

- Place the instrument close to a waste container or drain suitable for disposal of used reagents.
- Check that the drainage is suitable for disposal of chemical and biological waste.
- Check that the waste tubing is securely fastened in the drain.

Mandatory Action

Always use protective gloves when working with the waste container, waste tubing and when in contact with potentially biohazardous materials.

Instrument decontamination and disposal

Important

The European Directive 2002/96/EC on Waste Electric and Electronic Equipment (WEEE) aims to minimize the impact on the environment by prevention of waste. It is recommended to follow this procedure to allow waste collection and recycling of the equipment at the end of it's life cycle.

- The instructions for decontamination can be found on the Boule home page www.boule.se under User Support.
- If there are any question on how to follow this procedure, contact your local distributor for more information.

Warning

The analyzer should be considered as infected and the end user must follow a decontamination procedure before it is safe to hand over to a recycler.

Section 10: Parameter and System Information Messages

Section Overview

Introduction The Quintus has several parameter and system information messages related to the measured parameters and the instrument. These messages alert the operator of possible pathologic samples and parameter value and instrument errors.

Contents This section contains the following topics:

Topic	See Page
Out-of-Range and Information Message Indicators	78
System Information Messages	79
Parameter Messages	81
Parameter Limitations of Blood Cell Counters	82

10.1 Out-of-Range and Information Message Indicators

Description The instrument has several out-of-range, parameter, system information messages related to the measured parameters and the instrument. The messages are shown on the display and printouts.

Out-of-Range Indicators

- A parameter that is outside the "Normal Range", refer to Section 4.10 for Profile range setup, is either marked on the printout and display to indicate if the value is higher or lower than the pre-set "Normal Range" values.
  - '+' the value of the parameter is higher than the upper limit
  - '++' the value of the parameter is higher than the double of upper limit
  - '-' the value of the parameter is lower than the lower limit
  - '--' the value of the parameter is lower than the half of the lower limit
  - Parameter messages have also been assigned to the out-of-range indicators, see Section 10.3
- Another way to view out-of-range results quickly is to look at the colored range bar:
  - Red bar - Results Out-of-Range
  - Green bar- Results within range
- '*' the result for the affected parameter is not interpretable:
  - Out of sensor linearity
  - Measurement error
  - No Differential values will be shown if total WBC < 0.5 * 10^3 cells/µL
  - No MCV values will be shown if total RBC <0.60
  - No RDW values will be shown if total RBC <0.60 or MCV = 0
  - No MPV or PDW values will be shown if total PLT < 30

Displaying of Messages

- Both System Information and Parameter Messages can be accessed by pressing the **question mark** on the Detailed Results screen.
- Reagent alarm messages will display on the status bar when at least one of the reagent containers is running low, empty, or expired.

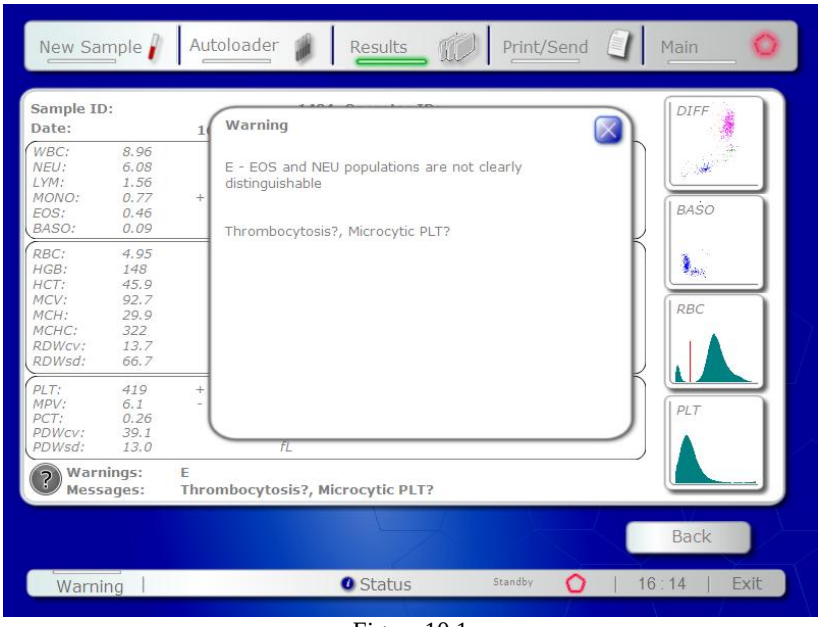
Abnormalities

Follow your laboratory's protocol for verification on all samples with anomalies and /or abnormal distributions signaled by the instrument. Pathological cells may vary in their stability towards lysing of their cytoplasmic membranes compared to normal cells, which may cause aberrations in the automated analysis. This also applies to the presence of normal non-pathological cells that have been subjected to chemotherapy or other treatments.

10.2 System Information Messages

Description

The system software monitors a number of analytical and system functions and will display information that indicates the possible attention of the operator. This information will alert the operator to check the system or sample or institute selected troubleshooting procedures. This information is presented on the touch screen as a code next to **question mark**, under "Warnings". Additional detail and recommendations may be accessed by either pressing the **question mark** on the touch screen or reviewing the printed report.

Step	Action
1	Press the question mark symbol on the touch screen to view more details on the System Information message.
	 Figure 10.1
2	Press the [X] to close the message box.

System Information Messages

Background messages			
Indicator	**Message**	**Description**	**Action**
b	RBC background high	Last accepted background result: RBC $\geq 0.01 \times 10^{12}$ cells/L	• Perform background measurement • Check cleanliness of the reagents and the Quintus system • If background, is not acceptable perform [CLEAN] • Repeat background measurement • If issue persists see Section 9.3: High background cleaning Treat result as "reduced reliability"
B	WBC background high	Last accepted background result: WBC $\geq 0.1 \times 10^{9}$ cells/L	
F	Differential background high	More than 100 cells detected during the 4-Diff background procedure.	
F	Baso background high	More than 100 cells detected during the Baso background procedure.	
H	HGB background high	Last accepted background result: HGB ≥ 0.2 g/dL	
p	PLT background high	Last accepted background result: PLT $\geq 10 \times 10^{9}$ cells/L	
Distribution Indicators (RBC,WBC)			
Indicator	**Message**	**Description**	**Action**
S	WBC Measurement Statistics Warning	The distribution of the WBC detection changes in time. It points to clogging, non-homogeneous sample, cold sample, partial coagulation of the sample.	• Re-analyze sample • Check the homogeneity, the temperature and the coagulation of the sample • Verify system has been correctly maintained, see Section 9.1 - 9.4
s	RBC Measurement Statistics Warning	The distribution of the RBC detection changes in time. It points to clogging, non-homogeneous sample, cold sample, partial coagulation of the sample.	
Clogging/Leakage Indicator (WBC, RBC)			
Indicator	**Message**	**Description**	**Action**
C	WBC clogging	Drift in the probe voltage of the WBC capillary. The main reason for this drift is the clogging of the capillary.	• Re-analyze sample • Verify system has been correctly maintained, see Section 9.1 - 9.4
c	RBC clogging	Drift in the probe voltage of the RBC capillary. The main reason for this drift is the clogging of the capillary.	
V	WBC Vacuum Warning	There is a (partial) clogging or leakage in the WBC part of measurement system. A faulty/ worn-out pump can create vacuum errors as well.	• Re-analyze sample • Perform a self-test • Verify system has been correctly maintained, see Section 9.1 - 9.4 • If vacuum problems persist then contact service.
V	RBC Vacuum Warning	There is a (partial) clogging or leakage in the RBC part of measurement system. A faulty/ worn-out pump can create vacuum errors as well.	
Linearity Indicator (RBC)			
Indicator	**Message**	**Description**	**Action**
M	Out of RBC linearity range	Inconsistency in RBC cell concentration.	• Check the sample homogeneity. • Re-analyze sample • Repeat the sample with manual pre-dilution.
m	Inconsistency in RBC cell concentration		• Check the sample homogeneity. • Re-analyze sample

WBC Differential Indicators (LYM, MONO, GRAN, EOS, BASO)			
Indicator	**Message**	**Description**	**Action**
A	4-DIFF populations are not clearly distinguishable	The 4-DIFF populations are not clearly distinguishable on the scattergram.	• Re-analyze sample • Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. • Verify system has been correctly maintained, see Section 9.1 - 9.4
D	MON and NEU populations are not clearly distinguishable	The MON and NEU populations are not clearly distinguishable on the scattergram.	
E	EOS and NEU populations are not clearly distinguishable	The EOS and NEU populations are not clearly distinguishable on the scatter-gram.	
Q	MON and LYM populations are not clearly distinguishable	The MON and LYM populations are not clearly distinguishable on the scattergram.	
X	4-DIFF: Not enough cells detected during counting.	Not enough cells detected during the 4-DIFF WBC differentiating.	
x	BASO: Not enough cells detected during counting.	Not enough cells detected during the Baso WBC differentiating.	
Y	Differential percentage error	Inconsistency in differential data.	• Please report to service representative
y	Baso percentage error		
PLT Interference (PLT)			
Indicator	**Message**	**Description**	**Action**
l	PLT-RBC gap is not clearly detectable on the PLT-RBC histogram	The PLT-RBC gap is not clearly detectable on the PLT-RBC histogram: small MCV, fractured RBC-s, aggregated PLT-s (cold blood), side-effect of blood-transfusion.	• Check the sample homogeneity. • Re-analyze sample • If the problem persists follow laboratory's protocol for verification of results.
Aspiration/Sampling Indicator			
Indicator	**Message**	**Description**	**Action**
W	Sampling Error	When air is detected by the blood detector in main sampling column during aspiration.	• Check that sample volume in tube is adequate • Re-analyze sample

10.3 Parameter Messages

Description

Parameter messages have also been assigned to the out-of-range indicators based on normal range values. More details on parameter limitation of the messages see Section 10.1 and 10.4.

Message	Indicator
Leukopenia?	-- WBC
Leukocytosis?	++ WBC
Neutropenia?	-- NEUT
Neutrocytosis?	++NEUT
Lymphopenia?	-- LYM
Lymphocytosis?	++ LYM
Monocytosis?	++ MONO
Eosinophilia?	++ EOS
Basophilia?	++ BASO
Anemia?	-, -- RBC

Message	Indicator
Polycythemia?	+, ++ RBC
Microcytic RBC?	-, -- MCV
Macrocytic RBC?	+, ++ MCV
Hypochromic?	-, -- MCHC
Hyperchromic?	+, ++ MCHC
Anisocytosis?	+, ++ RDW
Thrombocytopenia?	-- PLT
Thrombocytosis?	+, ++ PLT
Macrocytic PLT?	+, ++ MPV

10.4 Parameter Limitations of Automated Blood Cell Counters

Description This section describes the different factors that may interfere with HCT, HGB, MCV, MPV, PLT, RBC, RDW, WBC and WBC differential determination.

HGB Limitations	
Turbidity, in the blood sample, due to any number of physiological and/or therapeutic factors may produce falsely elevated HGB results. The instrument however, is compensated for this effect up to WBC concentrations of approximately 99.9 x 10^9/L.	
Limitation	**Description**
Unlysed Red Blood Cells	Increased turbidity may be seen in cases where the red blood cells are resistant to lysing. This condition will cause a falsely elevated HGB result but can be detected by monitoring the MCHC.
Leukocytosis	Extremely elevated WBC may produce falsely elevated HGB results due to turbidity. In case of extreme WBC counts, the following is recommended: The diluted sample should be centrifuged and the supernatant fluid checked on a spectrophotometer for turbidity.
Lipemia, hyperproteinemia and hyperbilirubinemia	Elevated lipids in the blood sample will give the plasma a "milky" appearance which may disturb the spectrophotometric measurement of HGB. Similar problems may occur with hyperproteinemia (high protein concentration) and hyperbilirubinemia (high bilirubin concentration). Accurate HGB determination can be achieved by using reference methods and a plasma blank.
Fetal blood	The mixing of fetal and maternal bloods may produce a falsely elevated HGB value.
MCV / HCT Limitations	
As HCT is the product of MCV x RBC, any erroneous result in MCV and/or RBC will produce an equal error in the HCT parameter.	
Limitation	**Description**
Red Blood Cell Agglutination	Agglutination of RBC may produce an erroneous MCV value and therefore a false HCT.
WBC	An excessive number of WBCs might cause interference within the RBC population and therefore a false MCV value.
Thrombocytosis (elevated PLT)	Excessive numbers of PLT, in most cases, do not interfere with the MCV parameter due to the use of the floating discriminator technology in the instrument.
PLT Limitations	
Measurement of low PLT levels may be influenced by circulating RBCs, which may cause falsely high results. Measurement of high PLT levels is influenced by coincidence factors (e.g. counting of two cells as one) which may produce falsely low results. The instrument is compensated for these effects by separate algorithms to produce linearity ranges according to the specifications	
Limitation	**Description**
Microcytosis (small RBC, low MCV)	Very small RBCs might falsely elevate a PLT count and affect the MPV. This effect is minimized in the instrument due to the use of a floating threshold (discriminator). By observing the PLT and RBC histograms, this effect is seen as an overlapping PLT/RBC area.
Agglutinated RBCs	Agglutinated RBCs might trap platelets and may give an erroneous low PLT count and affect the MPV. The presence of agglutinated RBCs is detected by monitoring the MCHC parameter and by careful examination of the stained blood film.
Giant platelets in excessive numbers	This may cause a low PLT count since they might fall within the RBC threshold range.
Chemotherapy	Cytotoxic and immunosuppressive drugs may increase the fragility of these cells, which may cause low PLT counts. Reference (manual) methods may be necessary to obtain an accurate platelet count.

Hemolysis	Hemolyzed specimens contain red cell stroma, which may elevate platelet counts.
A.C.D. blood	Blood anti coagulated with Acid Citrate Dextrose may contain platelet aggregates, which could depress the platelet count.
RBC inclusions	Erythrocyte inclusions may also produce a spuriously increased platelet count. (e.g. Howell-Jolly bodies, siderotic and basophilic granules)
Platelet agglutination	Clumped platelets due to poor collection techniques or platelet satellitosis caused by EDTA activation of immunoglobulins may cause a decreased platelet count and/or an elevated WBC count. The specimen should be recollected in sodium citrate anticoagulant and re analyzed for only the platelet count. The final PLT result must be corrected for the sodium citrate dilution effect.
MPV Limitations	
Limitation	**Description**
Giant platelets	Large platelets counted as RBCs will fall outside the PLT range and therefore lower the MPV.
Small erythrocytes	Very small RBCs might fall into the PLT region and might be counted as PLTs and therefore influence the MPV parameter.
Agglutinated erythrocytes	This may trap platelets and therefore affect the MPV parameter. Note that agglutinated erythrocytes may be detected by carefully examining the MCHC parameter and/or the stained blood film.
Chemotherapy	May also effect the size of the PLTs.
EDTA	Note that all samples collected in EDTA will not maintain a stable MPV. The PLTs will swell as a function of time and temperature.
RBC Limitations	
The red blood cell dilution contains all the cellular elements of the blood: RBC, WBC, and PLT. Platelets are not counted since the size falls below the discriminator threshold. Leukocytes are included in the RBC count, but since the ratio of RBCs to WBCs is approximately 1000:1, the introduced WBC count is almost negligible. Exceptions are noted below. Measurement of high RBC levels is influenced by coincidence factors (e.g. counting of two cells as one) which may produce falsely low results. The instrument is compensated for this effect by an algorithm to produce a linearity range according to the specifications	
Limitation	**Description**
Leukocytosis with concurrent anemia	In samples where the WBC is very high and at the same time the RBC is low, the WBC may cause a false increase in the RBC count. The WBC is always included in the RBC count, but the contribution is not significant under normal circumstances. The RBC count may be corrected by simply subtracting the WBC from RBC.
Agglutinated Red Blood Cells	This might cause a falsely decreased RBC count. Blood samples containing the agglutinated red blood cells may be identified by observing abnormal MCH and MCHC values, as well as by examination of the stained blood film.
Cold Agglutinins	IgM immunoglobulins which are elevated in cold agglutinin disease may lower RBC and PLT counts and increase the MCV.
RDW Limitations	
The red cell distribution width is a function of the RBC count and derived from the RBC histogram. In most cases, any error introduced in the MCV may also cause the RDW to be erroneous.	
Limitation	**Description**
Blood transfusions	Blood transfusions may raise the RDW significantly due to the presence of bi-modal populations.
WBC Limitations	
Measurement of high WBC levels is influenced by coincidence factors (e.g. counting of two cells as one) which may produce falsely low results. The instrument is compensated for this effect by an algorithm to produce a linearity range according to the specifications.	
Limitation	**Description**
Leukocytosis	WBC in concentrations that exceeds the linearity limits of the system will require dilution of the blood sample with diluent. Re-assaying the diluted sample will help to obtain the correct assay value.

Nucleated Red Blood Cells, NRBC	Immature, nucleated red blood cells are large and not lysed like mature RBCs, thus they will be classified as a WBC and may cause falsely elevated WBC and lymphocyte results. If the number of the NRBC is sufficient to activate the distribution alarm, such interference will be detected. An overview of a stained blood film can reveal the presence of NRBCs.
Unlysed Red Blood Cells	In particularly rare instances, the RBC in the blood sample may not completely lyse like expected. These non-lysed cells may be detected on the WBC histogram with a distribution alarm, or as an elevated baseline on the side of the lymphocyte population. Non-lysed RBCs will cause a falsely elevated WBC and lymphocyte count. (See also NRBC above)
Hemolysis	Hemolyzed specimen contains red cell debris, which may falsely elevate the WBC and/or PLT count. Hemolysis can be detected by looking at the color of the plasma in an EDTA-sample that has been allowed to sediment.
Leukemias	This disease state may result in a spurious low WBC count, if the leukocytes are more fragile than normal and becomes destroyed in the sample. The cell fragments will also interfere with the WBC differential parameters (LYM, GRAN and MONO). A falsely low WBC count may also be seen in patients with lymphocytic leukemias due to the presence of abnormally small lymphocytes, which may not be counted by the instrument.
Chemotherapy	Cytotoxic and immunosuppressive drugs may increase the fragility of the leukocytes, which may cause falsely low WBC counts.
Cryoglobulins	Increased levels of cryoglobin may cause elevated levels of WBC, RBC or PLT counts as well as HGB. Cryoglobulins may be associated with myeloma, carcinoma, leukemias, macroglobulinemia, lymphoproliferative disorders, metastatic tumors, autoimmune disorders, infections, idiopathic disease, aneurism, pregnancy, thromboembolic phenomena, diabetes, etc. The specimen can be warmed up to 37°C and re-analyzed immediately or a manual WBC, RBC or PLT count can be performed.
Multiple myeloma	The precipitation of proteins in multiple myeloma patients may give falsely elevated WBC counts.
Large lymphocytes, atypical lymphocytes, blasts, and basophils in excessive numbers	The presence of large or atypical lymphocytes, blasts, or an excessive number of basophils may interfere with the MONO cell area which otherwise consists mainly of monocytes.
Metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells in excessive numbers	The presence of excessive numbers of metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells may interfere with an accurate granulocyte count.
Lymphocyte count interference	The lymphocyte count is derived from the WBC count. The presence of nucleated red cells (NRBC), certain parasites and erythrocytes that are resistant to lysis may interfere with lymphocyte count.

Section 11: Technology

Section Overview

Introduction

This section describes the different methods and principles of measurement and calculations.

Contents

This section contains the following topics:

Topic	See Page
Measuring Principles	85
Impedance Method	85
Principle of HGB Measurement	86
Principle of Optical Measurement	87
Parameter Definitions	88

11.1 Measuring Principles

Description

This section describes the measuring principles of the Quintus.

General Measuring Principles

- Volumetric impedance method is used to determine cell counts regarding WBC, RBC and PLT parameters.
- Photometric measurement of light absorbance is used to determine hemoglobin (HGB) concentration.
- Optical measurement of light scattering and diffraction is used to determine 5-part WBC parameters.

Whole Blood Dilution

- WBC/BASO 1: 170
- RBC/PLT 1: 21250
- 4-part DIFF 1: 50

11.2 Impedance Method

Description

The volumetric impedance method counts and sizes cells by detecting and measuring changes in electrical impedance, when a particle within a conductive liquid passes through a small aperture.

- Each cell passing through the aperture – where a constant DC current flows between the external and internal electrodes – causes some change in the impedance of the conductive blood cell suspension.
- These changes are recorded as increases in the voltage between the electrodes.
- The number of pulses is proportional to the number of particles. The intensity of each pulse is proportional to the volume of that particle. The volume distribution diagrams of the particles are WBC, RBC, and PLT histograms. Pulses are counted only in channels (in terms of femtoliter, fL), which are between the lower and upper discriminators.

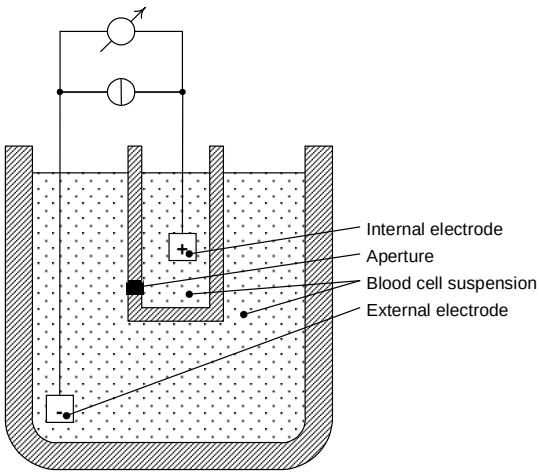


Figure 11.1

11.3 Principle of HGB Measurement

Description

The lysed sample dilution can be analyzed for HGB based on stable chromogen content. The reagent lyses the red blood cells, which release hemoglobin.

Subsequently, the HGB concentration is measured in a photometrical way across the WBC chamber. The actual sample HGB is calculated as a difference of a blank and a blood measure with and without illumination to reduce the effect of liquid refraction and disturbing light.

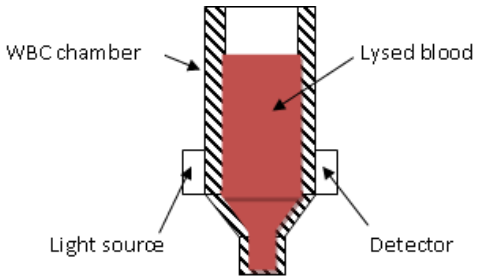


Figure 11.2

11.4 Principles of Optical Measurement

Description

Optical measurement of light scattering and diffraction is used to determine 5 part WBC parameters. The optical measuring head contains focused laser source to illuminate the stream of WBC blood cells. The intensity changes of the scattered laser light, coming from the cells, determined by the cell volume and structure. The changes recorded as an increase in the voltage of the detector system outputs.

The number of pulses is proportional to the number of particles. The intensity of each pulse is proportional to the volume and granularity of the blood cells. The WBC 5 population separation is based on the two dimension volume and granularity distribution diagram.

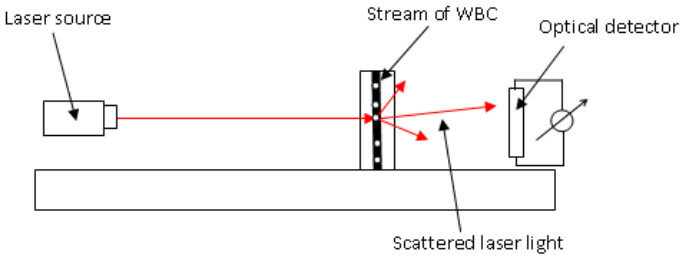


Figure 11.3

The intensity of scattered light is detected by an optical signal processing system. Light beamed onto a cell will diffract (scatter) depending on the cell's internal and external structures.

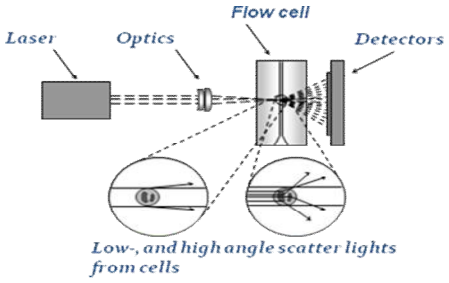


Figure 11.4

External structure (and the size of the cell) causes low angle scatter. Internal complexity causes high angle diffraction. The different angled lights are captured by optical sensors. Thus the system gets two independent parameters about one cell passing the light beam.

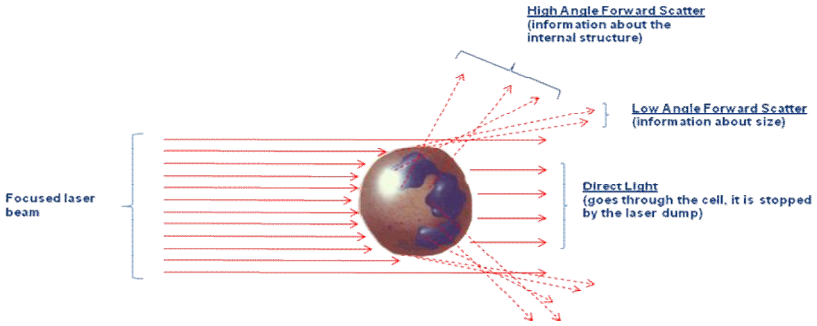

High Angle Forward Scatter
(information about the internal structure)
Low Angle Forward Scatter
(information about size)
Direct Light
(goes through the cell, it is stopped by the laser dump)
Focused laser beam

Figure 11.5

The data are plotted in a 2 dimensional coordinate system. Similar cells have similar scatter characteristics, and the analytical software can separate differentiate and identify them to provide 4DIFF and BASO scatter diagrams.

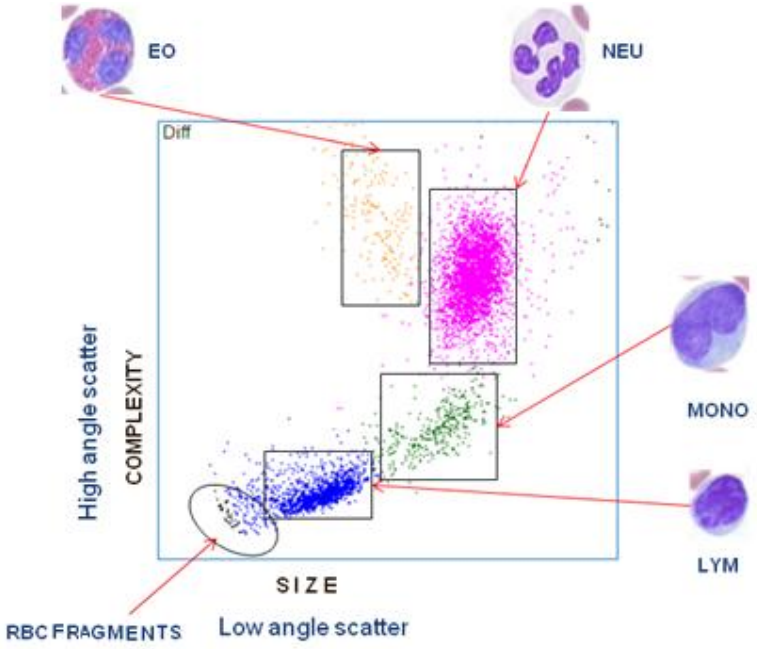


Figure 11.6

11.5 Parameter Definitions

Description

This section describes the parameter definitions that have not been defined yet in other sections.

MCV (Mean Cell Volume RBCs)

- Derived from the RBC distribution curve.
- RBC counts that are lower than 0.60 (displayed value) do not give a MCV value due to low statistical significance.

RDW (Red Cell Distribution Width)

PDW (Platelet Distribution Width)

- The distribution width of the erythrocyte or platelet population derived from the histogram at 20% of peak (RDW example seen below).

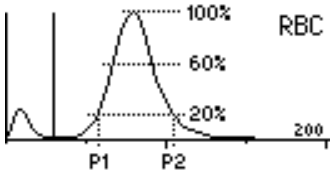


Figure 11.7

- xDW-SD = RDWcal x (P2 - P1) (fl), xDW-CV = RDWcal x 0.56 x (P2 - P1) / (P2 + P1) by the factor of 0.56 CV is corrected to the 60% cut
- The RDW parameter is only valid if the MCV value is not zero.
- The PDW parameter is only valid if total PLT < 30.

HCT (Hematocrit)	• Calculated from the RBC and MCV values. • HCT percentage = RBC x MCV x 100 • HCT absolute = RBC x MCV • If no MCV is derived from a sample due to too low a number of RBC cells, no HCT is calculated.
MPV (Mean Platelet Volume)	• The mean cell volume of the platelets is determined from the PLT size distribution curve. • MPV is not displayed in case of extremely low PLT counts (<30) due to high statistical inaccuracy of such a population.
HGB (Hemoglobin Concentration)	• Measured photometrically at 540 nm; each cycle blank measurement is performed on diluent • HGB = HGBcal x (HGBmeasured – HGBblank) • The HGB readings are slightly corrected for turbidity in case of extreme WBC counts.
MCH (Mean Cell Hemoglobin)	• Average hemoglobin content of erythrocytes, calculated from RBC and HGB values. • MCH = HGB / RBC
MCHC (Mean Cell Hemoglobin Concentration)	• Calculated from the HGB and HCT values. • MCHC = HGB / HCTabsolute • Unit of measurement is displayed according to the one chosen for HGB result (g/dL, g/L or mmol/L)
PDW (Platelet Distribution Width)	• The PDW parameter is calculated from the PLT distribution curve. The SD is calculated of the PLT size-distribution curve up to the actual setting of the (upper) PLT discriminator. • The PLT parameter is only valid if the MPV value is not zero.
LPCR (Large Platelets)	• The LPCR (Large Platelets Concentration Ratio) parameter is calculated from the PLT distribution curve. • Platelets that are larger than 12fl up to the discriminator are expressed in % of the total PLT count. • The LPCR parameter is only valid if the MPV value is not zero.
PCT (Packed Platelet Volume)	• Calculated from the PLT and MPV values • PCTpercentage = PLT x MPV x 100 • PCTabsolute = PLT x MPV

Section 12: Specifications

Section Overview

Introduction This section describes the specifications for the Quintus and its parameters.

Contents This section contains the following topics:

Topic	See Page
General	90
Short List of Specifications	91
Performance Specifications	92

12.1 General

Description This section describes the Quintus and its parts in general.

User Environment The operator works with a menu from which the desired program is chosen, e.g. discriminator settings.

Reagents Three external reagent reservoirs are used:

- Quintus 5-part Diluent (20 liter)
- Quintus 5-part Lyse (5 liter)
- Quintus 5-part Stopper (5 liter)

Control and Calibrator Four different products are available:

- Boule Con-5Diff (low, normal, high)
- Boule Cal-5Diff

Technology The Quintus is a fully automatic hematology analyzer designed to measure up to 24 parameters using whole blood from an open and closed tube mode.

5-Part WBC The instrument performs a 5-part WBC differential by means of a cyanide free hemolyzing reagent.

Protected Sample Memory A sample memory is available and protected against main power failures. The sample memory also contains a search function with selective printing and QC Options.

12.2 Short List of Specifications

Specifications (Short)

Measuring principle, RBC, WBC, PLT	Impedance
Measuring principle HGB	Light source: green LED with 540 nm wavelength Detector: light to frequency converter
Measuring principle 5-part Differential	Light scattering measurement:
Optical measurement	Light source: semiconductor laser diode with 650 nm wavelength and 7mW (Class IIIB laser module if the protective housing is closed) Quartz flow cell with hydro-dynamic focusing Detector: fiber optic coupled PIN Si photodiodes Internal safety interlock
Auto-alignment system	Optional. Horizontal and vertical calibration of laser beam position Fine calibration: with calibration material (Polystyrene micro-particle or Polystyrene microsphere, 5 µm)
Aperture length and diameter	WBC: 80 µm, RBC/PLT: 70 µm
Sampling system	Ceramic shear valve with 3 separated primary loops
Aspirated blood volume	~ 100 µl
Number of Samples per hour	> 60 samples
Sample type	Human whole blood (EDTA anticoagulant)
Parameters reported	WBC, LYM, MONO, NEU, EOS, BASO, LYM%, MONO%, NEU%, EOS%, BASO%, RBC, HCT, MCV, RDWsd, RDW cv, HGB, MCH, MCHC, PLT, PCT, MPV, PDWsd, PDWcv
Size distributions printed for	RBC, PLT and WBC differential
QC capabilities	Mean, SD, CV, Levey-Jennings plots and Xb plots
Carry-over	< 0.5%
Warning flags on parameter abnormalities	Yes
Setable normal ranges (profile limits)	Yes
Reagent and Instrument alerts	Yes
Built-in test / adjustment programs	Yes
Calibration	Manual and SW supported automatic mode
Language available	English menu and support for other languages
Software upgrade	Via USB
Memory capacity	100,000 records including flags, scatter- and histograms
Data processing	VIA C7 1.8 GHz processor
Data store	Windows® XP® Embedded
Display	800 x 600 color graphic LCD, landscape layout
External printing	Via USB port, any Windows® XP® Embedded compatible printer
Keyboard	Virtual incorporated keyboard (External keyboard option via PS/2 or USB)
Barcode reader	External via USB port Built-in barcode reader in Autoloader unit
Peripheral ports	4 USB (2.0), Ethernet, PS/2
Barcode reader input	Yes
Serial output	Yes (Conformed to standard EN 60950)
Main Voltage	100 – 240 V AC
Power consumption (maximum)	Max 400VA
Frequency	50 / 60 HZ
Main fuse	F 10A H 250V
Operating Temperature	15-30° C (59-86 °F)
Humidity (non-condensing)	Up to 80%

Instrument Dimensions	HxWxD = 515 x 410 x 465 mm (20 x 16 x 18 inches)
Autoloader Dimensions	HxWxD = 190 x 380 x 320 mm (8 x 15 x 13 inches)
Instrument weight	35 kg (≤ 77 lbs)
Autoloader weight	12 kg (≤ 26.4 lbs)
Diluent Consumption	Approximately 52 mL per analysis cycle.
Lyse Consumption	Approximately 7 mL per analysis cycle.
Stopper Consumption	Approximately 1 mL per analysis cycle.

12.3 Performance Specifications

Linearity-Regression and Linear Range

Linearity measured according to Boule I-1040 Section 8, based on Standard EP6-A.

Parameter	Linearity Range	Maximum Non-Linearity
WBC	0.5 – 99.9 x 10^9/L	± 0.4*10^9/L or 3%
RBC	0.30 – 7.00 x 10^{12}/L	± 0.05*10^{12}/L or 2%
PLT	20 – 1800 x 10^9/L	± 10*10^9/L or 3%
HGB	2.0 – 24.0 g/dL	± 0.2 g/dL or 2%

Displayed Range

Parameter	Displayed range
WBC	0.0 - 119.9 x10^9/L
RBC	0.00 – 14.00 x10^{12}/L
MCV	15.0 – 250.0 fL
PLT	0 - 1999 x10^9/L
HGB	0.0 – 35.0 g/dL

Accuracy

Linear correlation versus 5-part reference analyzer

Parameter	Correlation Coefficients (R)
WBC	≥ 0.98
RBC	≥ 0.98
HGB	≥ 0.98
HCT	≥ 0.97
PLT	≥ 0.97

Precision

Parameter	CV (%)	Range (precision achieved within)
WBC	≤ 3.0	4.7 x 10^3 / µL ≤ WBC ≤ 38 x 10^3 / µL
RBC	≤ 1.5	RBC ≥ 2.5 x 10^6 / µL
MCV	≤ 1.0	60 – 140 fL
PLT	≤ 5	PLT ≥ 100 x 10^3 / µL
HGB	≤ 1.5	HGB ≥ 6.0 g/dL

Section 13: Troubleshooting

Section Overview

Introduction

This section contains information needed to troubleshoot measurement related issues with the Quintus system

Contents

This Section contains the following topics:

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Shifted scattergram into the upper right corner	94
Scattergram shifted/bent left-right or up-down	94
Split populations on scattergram	95
Scattergram smeared to the right or upper side; Extremely over-gained scatter	95
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Long, smeared population and commet-like background	97
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Spreaded scattergram (high background)	99
No or very few celss on scattergram	99

13.1 Shifted (compressed) scattergram to the lower left corner

Description

This phenomenon is usually caused by a partial clog in the system or bad calibration of the scatter. The partial clog usually appears at the point where the flow-cell base narrows and the counting channel begins, it can cause a misaligned sample stream.

Possible reasons:

- Partially clogged flowcell in the optical head
- Bending or clogging at sheath injection port
- Laser power setting were changed and are wrong
- False or missing calibration of scattergram
- Misaligned optical head

Corrective actions:

- Check sheath tubing for bent or pinched portions
- Run flow cell backwash(Maintenance/ Cleaning/Flow cell)
- Check laser power settings*
- Perform manual cleaning of flow cell*
- Perform scatter calibration*

*To be performed by qualified service technician only

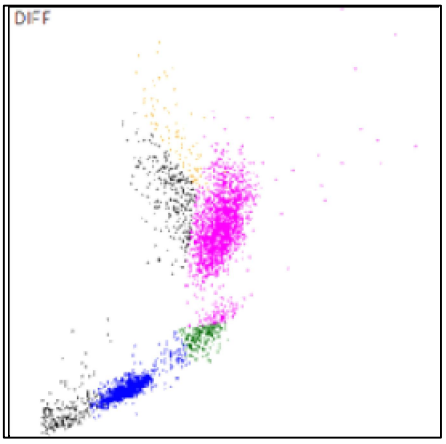

Figure 13.1

13.2 Shifted scattergram into the upper right corner

Description

This phenomenon is usually caused by bad scatter calibration or if scatter calibration was performed with partially clogged flow-cell and the clog has been removed. Also happens if the calibrator was expired or damaged.

Possible reasons:

- False or missing calibration of scattergram
- Laser power settings were changed
- Misaligned optical head

Corrective actions:

- Check laser power settings*
- Perform scatter calibration*

*To be performed by qualified service technician only

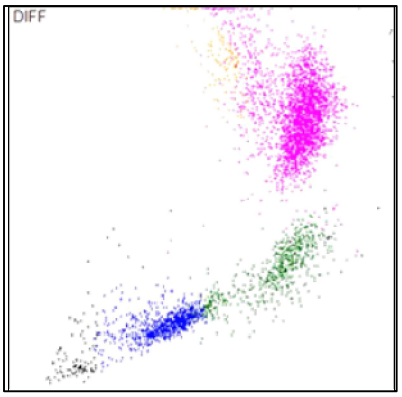

Figure 13.2

13.3 Scattergram shifted/bent left-right or up-down

Description

- The normally curved histogram is bent left or right. It is related with low angle gain problems.
- The normally curved histogram is bent down or up. It is related with high angle gain problems.
- Cell populations otherwise look OK, only the color identification is cutting them in half.

Possible reasons:

- Optical amplifier LOW and/or HIGH angle gain was changed
- Bad optical amplifier
- The optical head has been replaced, but scatter calibration wasn't performed

Corrective actions:

- Check optical amplifier gain factors*
- Perform scatter calibration*

*To be performed by qualified service technician only

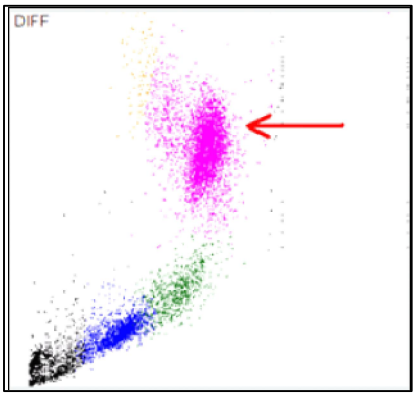

Figure 13.3

13.4 Split populations on scattergram

Description This phenomenon is usually caused by a partial clog in the system or misaligned laser head. The partial clog usually appears in the entrance point of the flow-cell, which can cause a misaligned or side moving sample stream.

Possible reasons:
- Partially clogged flowcell
- Bent or clogged sheath injection port
- Misaligned optical head

Corrective actions:
- Check sheath tubing for bent or pinched portions
- Run flow cell backwash(Maintenance/ Cleaning/Flow cell)
- Check laser power settings*
- Perform manual cleaning of flow cell*
- Perform scatter calibration*

*To be performed by qualified service technician only

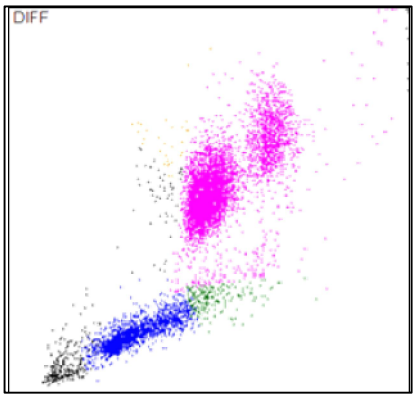

Figure 13.4

13.5 Scattergram smeared to the right or upper side; Extremely over-gained scatter

Description All cells generate extremely “intensive” signals in the optical amplifier. The system cannot compensate for the extreme high signals since the expected intensity range is exceeded.

Possible reasons:
- Scatter calibration values are too high
- Optical amplifier LOW and HIGH angle gain was changed
- Bad optical amplifier
- Optical head malfunction

Corrective actions:
- Check optical amplifier gain factors*
- Perform scatter calibration*

*To be performed by qualified service technician only

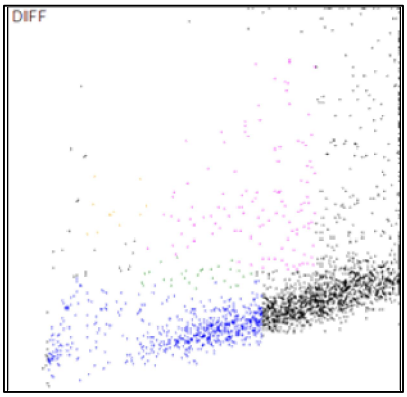

Figure 13.5

13.6 Triangular populations at lower left corner

Description The population on the background result can appear on control and human results as well. In that case it will be colored black or blue, as the system tries to identify it as some kind of irregular cell population.

Possible reasons:
- Noise in the laser light source.
  - (Noise is caused by an incorrect control of the laser diode's power. The laser can be changing modes because of the improper power control, and the optical analytical algorithms cannot compensate for these changes.
  - Mode hopping (fluctuations in laser light power) can also cause false pulses or intensity changes on the optical detector, and will be interpreted as small particles going through the flow cell)
- Misaligned optical head

Corrective actions:
- Check laser power settings*
- Change Laser Head*

*To be performed by qualified service technician only

Figure 13.6

13.7 High angle noise

Description The pictures below show similar human measurements.
- On the first picture there is good result.
- The second picture shows a result where high angle noise was present during the measurement.
  - The populations are spread upwards. The analytical algorithm could not follow up and the lower populations are cross coloured. The results are false and most of the times flagged with N flag.

Possible reasons:
- Noise in the laser light source (see point 13.6)
- Misaligned optical head

Corrective actions:
- Check laser power settings*
- Change Laser Head*

*To be performed by qualified service technician only

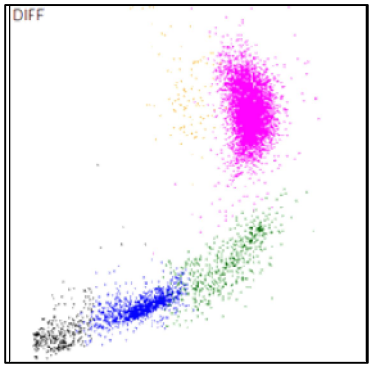

Figure 13.7

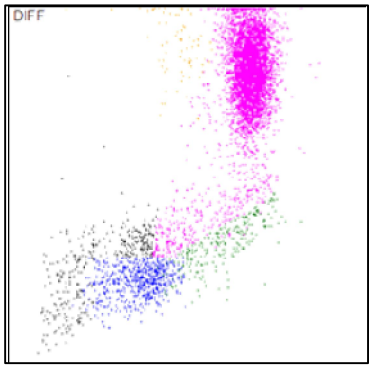

Figure 13.8

13.8 Dotted or continuous lines on X or Y axis end

Description The two lines can appear together, or independently.
They indicate high intensity particles, which could not be identified as cells thus cannot be represented in the “normal” analytical range

Possible reasons:
- Bubbles passing through the flow cell
- Improper tube connection in the sheath and/or optical sample path
- If it only appears in the 4diff scattergram:
  - Possible a TCU problem
  - Incorrect temperature
  - Incorrect mixing
  - Partial clog in the TCU tubing
- If it appears only in the BASO scatter:
  - Contaminated(dirty)WBC chamber
  - Malfunction of the WBC preheater module
- If the problem is present in BOTH scattergrams, then most probably air bubbles are formed somewhere inside of the optical head or in the related tubing

Corrective actions:
- Check all related tubing for presence of air bubbles
- Run self test, check TCU and WBC preheater temperature
- Perform Cleaning and Hard Cleaning

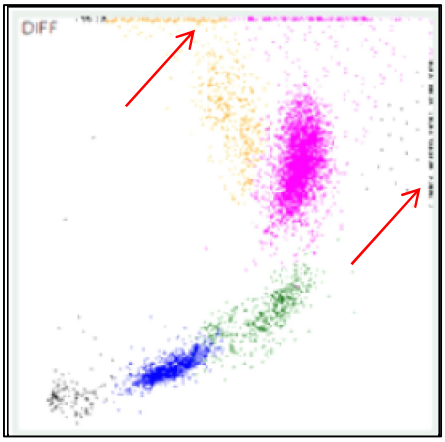

Figure 13.9

13.9 Long, smeared population and commet-like background

Description
- Baso scatter shows cells spread out upwards and obliquely.
- 4diff scatter is missing due to the high number of cells or showing small number of spread cells or sometimes just similar to the Baso scatter but with more cells.
- Background measurements contain one smaller-bigger, comet-like image in both scattergrams.
- This happens due to the high number of **un-lysed** cells which contaminate the optical head. The same happens if pure blood gets into the optical head due to pneumatical malfunction.

Possible reasons:
- Lyse and Stopper reagents are interchanged
- Stopper reagent is connected to both inputs
- Pneumatic error occurred during a previous human or control measurement and the optical head got contaminated

Corrective actions:
- Check if reagents are connected to corresponding inputs
- Run Cleaning

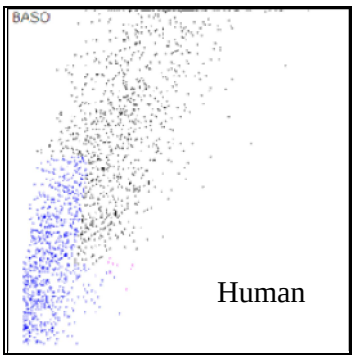

Figure 13.10

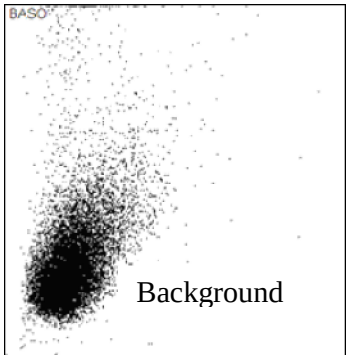

Figure 13.11

13.10 Over-lysed populations

Description

The 4diff scatter shows an overlysed condition (for different patient's fresh blood). The populations are not concentrated and has spread out cells from them pointing to the lower left corner. Populations are smearing together along the path of the displayed curved arrow.

Possible reasons:

- Lyse reagent is connected to Stopper input as well
- TCU temperature is too high,
- Human blood is too old and too sensitive against the lyse reagent

Corrective actions:

- Check if reagents are connected to corresponding inputs
- Run Self Test and check TCU temperature
- Run control measurement from a freshly opened control tube

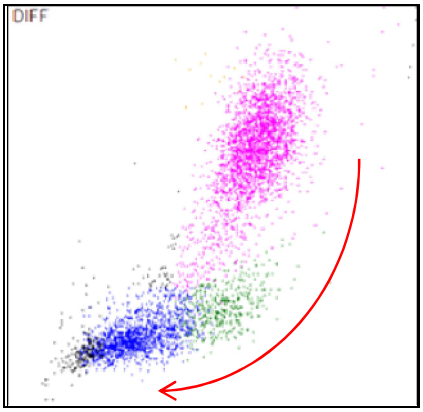

Figure 13.12

13.11 Concentrated (RBC ghost) scattergram

Description

This image shows a concentrated group of cells. Cells seems to be unaffected by the chemical reactions that should separate them to different populations.

- This scattergram can be seen on human results as well.

Possible reasons:

- Clogged TCU - RBC ghost population appears
- Partially clogged TCU, the previous sample interferes with next one
- Mechanical error or jam occurred during previous measurement, or sampling and the SW stopped. During restart, whole blood, or insufficiently diluted blood got into the flow cell, or to the injector area

Corrective actions:

- Run Cleaning
- Perform manual cleaning of TCU*

*To be performed by qualified service technician only

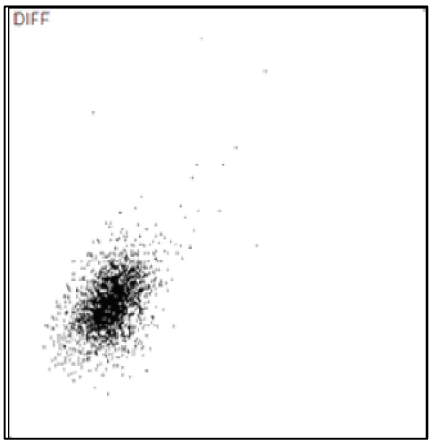

Figure 13.13

13.12 Spreaded scattergram (high background)

Description

- If the sheath puffer or the diluent container is contaminated, similar scatters can be seen on both optical channels.
- Optical background can be vertical or horizontal spreading of black dots like shown on the pictures.
- Running backgrounds or draining and refilling the sheath puffer decreases the background.

Possible reasons:

- Sheath puffer or optical head contamination
- Contaminated Diluent. In this case PLT background is also high

Corrective actions:

- Run Cleaning
- Run Internal Diluent Reservoir cleaning
- Open a new Diluent container

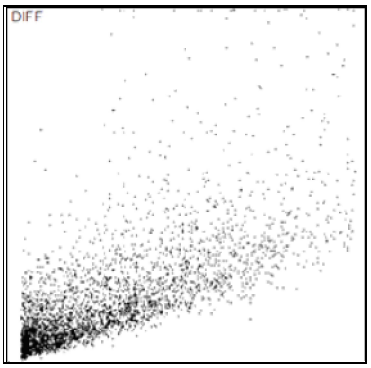

Figure 13.14

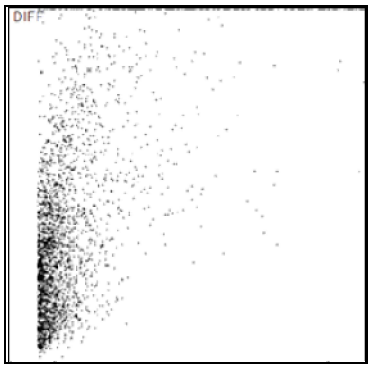

Figure 13.15

13.13 No or very few cells on scattergram

Description

- Whatever is displayed on the scattergram (and also on histograms) was actually measured by the optical system.
- Just a few cells have passed through the laser head
- When both scattegrams are lack of cells it can indicate a possible optical head problem.

Possible reasons, if only 4-Diff scatter is affected:

- No cells and result is flagged with DA or DQ: the analysis cannot be performed, because the scattergram is probably having real cells, yet the system does not display it, because the populations are overlapped
- No cells and result is flagged with X or low number of cells
- Sampling error – insufficient amount of blood in the primary sampling loops
- Partially clogged TCU, or limited sample flow through the TCU
- TCU related tube has come off.
- TCU related valve is not working properly

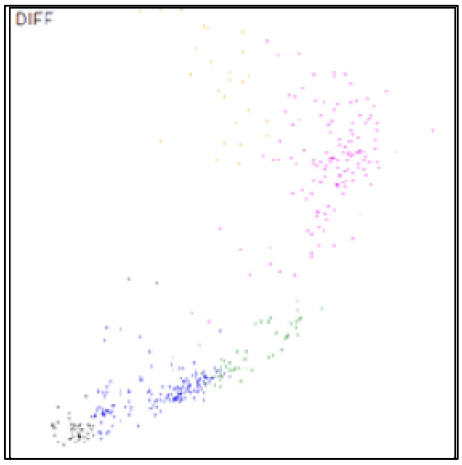

Figure 13.16

Possible reasons, if only BASO scatter is affected: • Sampling error – insufficient amount of blood in the primary sampling loops • WBC chamber related tube path clogged or tube come off **Possible reasons, if both scatters are affected:** • Blood sample is low on WBC parameter • Partial or total clogging of flowcell • Sampling error – insufficient amount of blood in the tube, or something blocked the sample path into the shear valve • Sheath tube coil (below the shear valve) is pinched, full of bubbles, or blocked • Tube is loosen or has come off from the dilutor, optical head, or from sample path • No laser light • A totally misaligned optical system (typically an incorrect value was sent to the auto alignment motor, and it was saved). The laser light is off from the counting channel **Corrective actions:** • Run Cleaning • Run Self Test, check laser parameters • Check sampling • Check tubing for loosen connections, leaking, presence of air bubbles • Perform manual cleaning of TCU* *To be performed by qualified service technician only	

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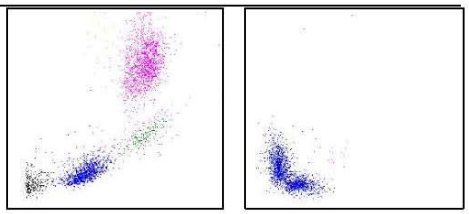
Appendix A

Boule

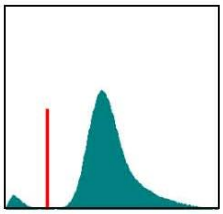
21/10/2010 14:15

Sample ID	9490	Operator ID	
Date	15/09/2010 10:58	Mode	Human

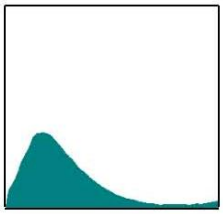
Parameter	Result		Limit		
WBC	7.31	$10^3/\mu L$	5.00	-	10.00
NEU	3.79	51.9 %	2.00	-	7.50
LYM	2.86	39.1 %	1.30	-	4.00
MONO	0.50	6.8 %	0.15	-	0.70
EOS	0.12	1.6 %	0.00	-	0.50
BASO	0.04	0.6 %	0.00	-	0.15



RBC	5.38	$10^6/\mu L$	4.00	-	5.50
HGB	154	g/L	120	-	174
HCT	47.5	%	36.0	-	52.0
MCV	88.3	fL	76.0	-	96.0
MCH	28.6	pg	27.0	-	32.0
MCHC	324	g/L	300	-	350
RDWsd	55.7	fL	30.0	-	150.0
RDWcv	12.3	%	0.0	-	16.0



PLT	219	$10^3/\mu L$	150	-	400
PDWcv	37.7	%		-	
PDWsd	18.3	fL		-	
MPV	8.5	fL	8.0	-	15.0
PCT	0.19	%		-	



Warnings

Messages